2017

Mike Dourson Confirmation Hearing Preparation

QUESTIONS AND ANSWERS

OFFICE OF CHEMICAL SAFTEY AND POLLUTION PREVENTION

Confirmation Hearing Preparation: Questions/Answers
for Mike Dourson, Nominee for OCSPP Assistant Administrator

Potential Areas of Questioning

OCSPP Leadership (OCIR to develop)
- Nancy Beck (NGO blogs, press)

Alleged Conflicts of Interest (OCIR to develop)
- Past chemical industry clients (NGO blogs, press)

FY18 Budget
- Zeroing out of STAG
- Zeroing out of P2
- Significant cut to TRI
- Zeroing out of Lead Risk Reduction
- Zeroing out of Science Policy and Biotech
- Zeroing out of Endocrine Disruptors
- Zeroing out of Categorical Grants
- How hiring freeze/FTE reductions are likely to affect programs?
- How may reductions to ORD affect OCSPP Programs?

Office of Pesticide Programs (OPP)
- Certification of Pesticides Applicators Rule
- Worker Protection Standard
- Chlorpyrifos
- Dicamba
- Glyphosate
- Organophosphates
- Endangered Species Act
- PRIA4
- Neonicotinoids
- Atrazine

Office of Pollution Prevention and Toxics (OPPT)
- TSCA Implementation Activities
- TSCA Framework Rules
    - Active/Inactive Inventory Rule
    - Prioritization Rule
    - Risk Evaluation Rule
- First 10 Chemical Risk Evaluations
- New Chemicals Reviews
- TSCA CBI
- Safer Choice Program
- Formaldehyde
- Lead

- Polychlorinated Biphenyls (PCBs)
- Per- and Polyfluoroalkyl Substances (PFOA/PFAS)
- TSCA Section 6 Rules - TCE and Methylene Chloride/NMP
- Views on the role of enforcement in effective implementation
- Views on how Exec Orders on burden/regulation reduction will affect implementation
- Does EPA have enough information to evaluate the risk of most chemicals?

Office of Science Coordination and Policy (OSCP)

- OSCP Science Coordination Overview
- Science Advisory Committee on Chemicals (SACC)
- Endocrine Disruptor Screening Program (EDSP)
- FIFRA Science Advisory Panel (SAP)

FY18 BUDGET

P2 Program Elimination

Q. ***Why did EPA choose to eliminate funding for the Pollution Prevention (P2) Program? What are the impacts of this elimination?***

Answer:

- The FY 2018 President's budget eliminates programs that are mature, duplicative, or can be absorbed into other programs, are equally conducted or eligible under other programs, or are or could be state and local responsibilities
- The FY 2018 President's Budget is the Administration's request to Congress for appropriations; EPA's funding levels for FY 2018 will be determined by Congress through the annual congressional appropriations process.

Background:

- OCSPP's P2 activities include the Safer Choice labeling program, development of Environmentally Preferable Purchasing (EPP) standards, supporting Green Chemistry/Engineering, and provision of P2 related grants, information and support to States.
- EPA has made great strides in carrying out the intent of Congress to encourage reductions in the generation, use and release of hazardous substances while helping businesses reduce operational costs
- Based on previous investments in P2 solutions made under the P2 Program in previous year, EPA expects partners will be able to continue to share best practices and seek additional pollution prevention solutions.
- Within EPA, programs implementing environmental laws will continue to pursue approaches that prevent pollution at the source. For example, pollution prevention has, and is expected to be, a key tool in implementing the Toxics Substances Control Act, as amended in 2016, which requires EPA, in promulgating rules to mitigate unreasonable risk, to consider technically and economically feasible alternatives that benefit health or the environment (TSCA Section 6(c)(2)C).

Toxics Release Inventory (TRI) Reduction

Q. ***What is the expected impact of the reduction to the Toxics Release Inventory Program?***

Answer:

- The proposed funding reduction will eliminate funding for the TRI National Training Conference, TRI University Challenge, TRI Information Center, TRI Tools, and other TRI communication initiatives.
- The FY 2018 President's Budget is the Administration's request to Congress for appropriations; EPA's funding levels for FY 2018 will be determined by Congress through the annual congressional appropriations process.

Background:

- EPA will continue to meet its requirements regarding the collection of chemical release data and making said data available to governments and the public. Additionally, as required by the Emergency Planning and Community Right-to-Know Act (EPCRA), the agency will respond to EPCRA petitions regarding TRI within 180 days after receipt.
- The Toxics Release Inventory (TRI) program supports the EPA's mission by annually publishing, for the public, release and other waste management (e.g., recycling) and pollution prevention data on over 650 toxic chemicals from approximately 20,000 industrial and federal facilities. The TRI Program is a premiere source of toxic chemical release data for communities, non-governmental organizations, industrial facilities, academia, and government agencies.

Lead Risk Reduction Program Elimination

Q. ***Why did EPA choose to eliminate funding for the Lead Risk Reduction Program? What are the impacts of this elimination?***

Answer:

- The FY 2018 President's budget eliminates programs that are mature, duplicative, or can be absorbed into other programs, are equally conducted or eligible under other programs, or are or could be state and local responsibilities.
- The FY 2018 President's Budget is the Administration's request to Congress for appropriations; EPA's funding levels for FY 2018 will be determined by Congress through the annual congressional appropriations process.

Background:

- The Lead Risk Reduction Program is a mature program that in its entirety will not be eliminated, certain critical aspects of the program will continue. At a minimum, EPA will continue to provide firm and individual certifications for safe work practices for lead-based paint abatement and renovation and repair efforts. EPA also will continue to provide for operation and maintenance of the online database (FLPP) that supports the processing of applications for training providers, firms, and individuals. These aspects of the lead program will be funded at $500K and 2 FTE through the Chemical Risk Review and Reduction program.
- The United States has made tremendous progress in reducing lead exposure, resulting in lower childhood blood lead levels over time. Childhood blood lead levels have declined substantially since the 1970s; 1.2% of children had BLL $\geq$ 5 µg/dL in 2011–2014, compared with 26% in 1988–1994 and 8.7% in 1999-2002. The progress that has been made has resulted, in part, from the implementation and enforcement of multiple U.S. regulations, including those under EPA's Lead Risk Reduction Program established in 1992, which aim to reduce childhood lead exposures or ameliorate its effects.

Science Policy and Biotechnology Program Elimination

Q. ***What is the expected impact of the elimination of the Science Policy and Biotechnology Program?***

Answer:

- The FY 2018 President's budget eliminates programs that are mature, duplicative, or can be absorbed into other programs, are equally conducted or eligible under other programs, or are or could be state and local responsibilities.
- The FY 2018 President's Budget is the Administration's request to Congress for appropriations; EPA's funding levels for FY 2018 will be determined by Congress through the annual congressional appropriations process.

Background:

- The science advisory committee oversight required by FIFRA and TSCA will be supported by the pesticides and toxics program offices utilizing their programmatic resources.

Endocrine Disruptor Screening Program Elimination

Q. ***What is the expected impact of the elimination of the Endocrine Disruptor Screening Program?***

Answer:

- The FY 2018 President's budget eliminates programs that are mature, duplicative, or can be absorbed into other programs, are equally conducted or eligible under other programs, or are or could be state and local responsibilities.
- The FY 2018 President's Budget is the Administration's request to Congress for appropriations; EPA's funding levels for FY 2018 will be determined by Congress through the annual congressional appropriations process.

Background:

- The Endocrine Disruptor Screening Program (EDSP) is a mature program that was established in 1996 under authorities contained in the Federal Food, Drug and Cosmetic Act (FFDCA) and the Safe Drinking Water Act (SDWA) amendments. The ongoing functions of the program can be absorbed into the pesticides program office.
- Current activities within the EDSP include transitioning to the use of high throughput screening (HTS) and computational toxicology (CompTox) tools to screen thousands of chemicals for endocrine activity, establishing policies and procedures for screening and

testing, and evaluating data to ensure chemical safety by protecting public health and the environment from endocrine disrupting chemicals.

Categorical Grant Elimination / Reduction in Funding

Q. ***Why did EPA choose to eliminate funding for the Lead and Pollution Prevention Categorical Grants to States and Tribes and reduce funding for the Pesticides Implementation Grants? What are the impacts of these eliminations and reductions?***

Answer:

- In the FY 2018 President's Budget, EPA is prioritizing resources to support the agency's mission, the budget supports a renewed focus on achieving its statutory responsibilities to protect the nation's air and water quality. The Agency will work with its state and local partners to identify shared priorities and make progress in achieving them.
- The FY 2018 President's Budget is the Administration's request to Congress for appropriations; EPA's funding levels for FY 2018 will be determined by Congress through the annual congressional appropriations process.

Background:

- Lead - Although EPA's grant funding for Lead-based paint to states is proposed for elimination, states could choose to fund programs targeted at reducing lead based paint poisoning and continue activities that have been supported by EPA. Additionally, other forms of lead exposure (in water and air) continue to be addressed through a host of federal and state programs.
- P2 – Existing P2 partners & grant recipients are expected to be able to continue to share best practices and build on successes already achieved using P2 Categorical Grant resources.
- Pesticides - Due to the funding reduction renewed focus will be placed on streamlining core activities and reducing duplication. The EPA will work with states and Tribes to target funds to core requirements while providing flexibility to address particular priorities.
- FY 2017 Enacted Funding Levels – P2: $4,765.0K; Lead: $14,049.0K; Pesticides: $12,701.0K
- FY 2018 President's Budget Funding Levels – P2: $0.0K; Lead: $0.0K; Pesticides: $8,874.0K

Hiring Freeze / FTE Reductions

Q. ***How will the continued EPA hiring freeze and proposed FTE reductions in the FY 2018 President's Budget impact OCSPP?***

Answer:

EPA will streamline existing business processes and eliminate unnecessary redundancies to utilize staff in line with the FY 2018 budget and with the agency's top human health priorities.

Background:
The FY 2018 President's Budget reduces OCSPP's overall FTE by 159.6, from 1,156.0 in FY 2017 to 996.4 in FY 2018.

Impacts of ORD Reductions on OCSPP

Q. ***How will the proposed reductions in the FY 2018 President's Budget impact OCSPP's ability to complete its mission?***

Answer:
In FY 2018, the EPA will prioritize science and research activities directly tied to statutory requirements and inquiries into environmental and human health sciences. Science and research will be streamlined to support the agency's program and will prioritize the most important work to protect human health and the environment.

Background:
ORD's "Chemical Safety and Sustainability" Research Program is funded at $61.7M in the FY 2018 President's Budget, a $27.5M reduction compared against the FY 2017 President's Budget. This research program includes funding for Endocrine Disruptors and Computational Toxicology research.

OFFICE OF PESTICDE PROGRAMS

Certification of Pesticide Applicators Rule

Q. ***Why did EPA extend the effective date of the certification rule?***

Answer:
The effective date has been delayed to allow time for a substantive review of the questions of fact, law and policy associated with the rule, in accordance with the Presidential directives provided in the memorandum of January 20, 2017.

The extension also allows time for EPA to consider revisions to the certification rule based on input received through the Regulatory Reform Agenda efforts. If EPA's Regulatory Reform Agenda efforts identify a need for additional changes to the certification rule, EPA will pursue such changes through notice and comment rulemaking.

Background:
The effective rule date was delayed from March 6, 2017 to May 22, 2018, The Presidential directives provided in the memorandum of January 20, 2017 was from Reince Priebus, Assistant to the President and Chief of Staff, titled "Regulatory Freeze Pending Review," and the principles identified in the April 25, 2017, Executive Order "Promoting Agriculture and Rural Prosperity in America."

EPA's Certification of Pesticide Applicators rule (certification rule), 40 CFR Part 171, sets federal standards for states, tribes and federal agencies to administer programs to certify applicators of restricted use pesticides (RUPs). The certification rule establishes minimum standards of competency for pesticide applicators that apply or supervise the use of RUPs, covering private and commercial applicators, and those using RUPs under their direct supervision. The certification programs are conducted by pesticide lead agencies in states, territories, tribes and federal agencies. The certification rule has been in place since 1974; a revised rule was issued in the Federal Register on January 4, 2017.

On August 24, 2015, EPA published a Federal Register Notice soliciting public comments on a revision to the 1974 Certification of Pesticide Applicators of restricted use pesticides rule. After extensive stakeholder review of the original regulation and an analysis of over 700 distinct comments, EPA published a final rule on January 4, 2017 with an effective date of March 6, 2017. EPA extended the effective date to March 21, 2017 by rule on January 26, 2017, and subsequently extended it again to May 22, 2017 by rule issued March 20, 2017. In accordance with the January 20, 2017 Presidential directives "Regulatory Freeze Pending Review," and the principles identified in the April 25, 2017 Executive Order "Promoting Agriculture and Rural Prosperity in America," on May 5, 2017 EPA gave a four-day public comment period on a proposed delay of the effective date from May 22, 2017 to May 22, 2018. On May 22, 2017, EPA announced an interim effective date of June 2, 2017 to consider and respond to public comments received in regard to the proposed May 22, 2018 extension. On June 2, 2017, EPA announced the effective date of May 22, 2018.

Q. ***What is the status of the lawsuit regarding the process EPA used to delay the effective date? Will the effective date change again?***

Answer:
The extension of the certification rule's effective date is under legal challenge, so EPA cannot comment on the delayed date at this time.

Background:
In June 2017, a group* of nonprofit farmworker organizations submitted a challenge in the 9th District Court to EPA's delay of the Certification of Pesticide Applicators Rule. The group asserted that EPA violated the Administrative Procedure Act (APA) and the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA) by issuing "repeated, unlawful" delays of the Rule. EPA published two Federal Register Notices delaying the effective date of the Rule without soliciting public comment. In a third Federal Register Notice, EPA gave the public four days to submit comments on a one-year delay, whereas the group asserts that the APA requires a minimum 30-day comment period. Also, the group asserts EPA failed to provide adequate justification for a one-year delay in contrast to EPA's justification that the final Rule was necessary to comply with FIFRA obligations to prevent unreasonable adverse effects to applicators, workers, the public, or the environment. With this challenge, the group is asking the court to vacate the delays which would make the rule effective immediately. (*Pineros Y Campesinos Unidos del Noroeste, United Farm Workers, Farmworker Association of Florida, California Rural Legal Assistance Foundation, and Pesticide Action Network North America)

Q. ***What is the impact to human health and the environment if implementation is delayed?***

Answer:
The existing certification programs remain in effect. The issues identified during the development of the revised rule will be addressed when the revised requirements are implemented. Once the rule is effective, certifying authorities will have three years to revise and submit their certification plans to EPA for review.

Background: The revised Certification of Pesticide Applicators of restricted use pesticides (RUPs) rule seeks to enhance and improve the competency of certified RUP applicators and persons working under their direct supervision. The rule aims to protect applicators from exposure while working with RUPs, and the public and the environment from exposure to RUPs as a result of misapplication by applicators. In the FIFRA-required cost-benefit analysis, EPA found that the revised requirements of the 2017 revised regulation would help prevent illness and injury to applicators, the public and the environment.

Q. ***Some states will require legislative and/or regulatory changes to implement the revisions. How is EPA addressing this burden?***

Answer:
The current final rule provides options and flexibility for implementing the requirements. EPA will continue to work with and engage in open and transparent discussions and negotiations with the states and certifying authorities as they develop revised plans.

Background:
EPA extended the effective rule date which allows additional time for EPA to consider revisions to the current rule based on input received through the Regulatory Reform Agenda efforts.

If states want to certify pesticide applicators, FIFRA requires that all state pesticide applicator authorities (usually state departments of agriculture) have an EPA-approved Certification Plan. The contents of the Certification Plan are outlined in the Certification of Pesticide Applicators of restricted use pesticides rule. Some states will have to make legislative and regulatory changes to their certification program. EPA-approval of the Certification Plan is contingent upon such changes.

In response to commenters' concerns expressed during the public comment period for the proposed rule, EPA adopted a final rule with options for more flexible time frames to implement the requirements. The final rule lengthens the time for certifying authorities to submit revised certification plans and allows EPA discretion to grant certifying authorities more or less than two years to implement newly approved plans. Certifying authorities will have three years to revise and submit their certification plans. The final rule adds a provision to grant conditional approval of certification plans. Certifying authorities unable to complete necessary legislative and regulatory changes before submitting their new certification plan would be allowed to submit a draft plan conditioned upon those changes becoming effective.

Q. ***How can EPA justify the rule's additional burden? What will this cost?***

Answer:
The rule will improve the pesticide applicator certification and training program substantially and EPA decided that the benefits justify the costs. Pesticide safety education helps applicators improve their abilities to avoid pesticide misuse, spills and harm to non-target organisms. Trained and competent applicators are more likely to apply pesticide products without causing unreasonable adverse effects and use restricted-use pesticides properly than applicators who are not adequately trained or properly certified.

The estimated cost of the revisions is about $31.3 million annually. The estimated annual benefits of the changes are between $13.2 and $26.3 million.

Background:
In addition to core pesticide safety and practical use concepts, certification and training assures that applicators possess critical information on a wide range of environmental issues, such as endangered species, water quality, worker protection, and protecting non-target organisms. In the 2015 Federal Register Notice for public comment on the 1974 Certification of Pesticide Applicators, EPA estimated costs to the affected industries would increase by approximately $46.9 million annually because of the proposed revisions. In the 2017 final regulation, the estimated increase in burden to affected industries was reduced to approximately $24.8 million annually. The reduction in costs is attributed to the changes EPA made in the final regulation to accommodate the needs of the affected industries.

EPA estimated the annual benefits of the changes between $13.2 and $26.3 million.

- This estimate only includes avoiding reported acute pesticide incidents to people – it does not quantify the potential benefits to avoiding chronic illnesses that may be related to use of restricted-use pesticides (RUPs) or the willingness to pay to avoid acute effects of pesticide exposure beyond cost of treatment and loss of productivity, nor does it quantify the potential benefits to the environment from avoiding misapplication of RUPs.
- This estimate does not account for underreporting of pesticide incidents, which when factored in could increase the potential benefits of the rulemaking to between $65.9 and $131.6 million annually.

EPA estimated the cost of the revisions to the rule to be about $31.3 million annually.

- These costs are the incremental costs of complying with the new requirements in the revised rule, not the total costs of administering certification programs.
- These costs would fall mostly on certified applicators and those working under their direct supervision, but there would also be some costs for States, Tribes, and Federal agencies that administer certification programs.
- This estimate includes the cost of requiring applicators to be certified in new categories, of requiring training on safe pesticide application and protecting those working under the direct supervision of certified applicators, of implementing a mandatory timeframe for recertification of pesticide applicators, and of establishing a minimum age of 18 for persons to be able to use RUPs (with a limited exception).

Q. ***What resources and funding will be provided to support implementation?***

Answer:
EPA will continue to give priority to funding the states and tribes for these programs through the state and Tribal Assistance Grants program; and provide funding to pesticide safety education programs from service fees collected under the Pesticide Registration Improvement Act and subsequent reauthorizations.

Background:
EPA recognizes that certifying authorities and pesticide safety education programs will need to devote resources to additional training, manual development, exam development and review, exam administration, and other services that support certification and education of pesticide applicators in conformance with the final rule.

Under the existing law, EPA must commit at least $500,000 of the funds collected by pesticide registration-related actions to support the pesticide safety education program to assist in the operation of their certification programs.

The amount of funds is contingent upon EPA's budget and has remained stagnant over the years. EPA attempts to accommodate State's needs by providing resources such as applicator training materials and exams developed through cooperative agreements with nonprofit entities.

Q. ***When will guidance be available to states, tribes and federal agencies to revise their certification plans?***

Answer:

EPA anticipates further dialogue with certifying authorities, as needed, to provide interpretations of and guidance on regulatory language and provisions. Guidance will be developed soon after the effective date to allow for sufficient time between the effective date and due date for certifying authorities to submit their revised certification plans to EPA for review and approval, although no date has been determined.

Background:

FIFRA requires states, tribes, territories and federal agencies ("certifying authorities) to have EPA-approved Certification Plans before they can certify applicators of restricted use pesticides. EPA will develop guidance to help certifying authorities identify and implement the necessary changes to their Certification Plan in compliance with the revised regulations. Much of the work on developing guidance will be done by staff in the Office of Pesticide Programs, but with input and coordination with the Regions (who will ultimately be approving the plans), Office of General Counsel and Office of Enforcement and Compliance Assurance. The guidance will be developed as possible based on available staff and competing priorities.

Q. ***Why did EPA require a minimum age of 18 in the certification rule? Do you plan to revise this?***

Answer:

A minimum age requirement was added as a reasonable precaution to protect adolescents from pesticide exposures because of the potential impact of pesticides on further development and because adolescents may not properly appreciate (and take appropriate steps to avoid) the risks of potential pesticide exposure.

EPA has received comments requesting revisions to the minimum age requirements which are currently being considered by the Agency within the Regulatory Reform Agenda efforts.

Background:

Although EPA is not able to measure the full benefits that accrue from reducing chronic exposure to pesticides, well-documented associations between pesticide exposure and certain cancer and non-cancer chronic health effects exist in peer reviewed literature. While statistical associations have been observed in studies that estimate the relation between pesticide exposure and chronic health outcomes such as cancer, the causal nature of these associations has not yet been determined; thus quantifying the magnitude of the chronic health risk reduction expected as a result of pesticide exposure reduction is not possible. Based on what is known about the potential for biologically active chemicals generally to disrupt developmental processes, it is reasonable to have heightened concern for adolescents under the age of 18 in situations where they face particularly high pesticide exposures and exposure to pesticides classified as RUPs. Although EPA agrees that certification exams are a gauge of competency, they are not the only relevant gauge, and EPA decided age should be a consideration for determining competency. Generally prohibiting adolescents under the age of 18 from applying RUPs will protect them from any potential risks of using RUPs, ensuring that adolescents do not cause or suffer

unreasonable adverse effects from using RUPs. Based on the comments received on the proposed rule and an evaluation of existing literature related to adolescents' development of maturity and judgment, EPA decided that the benefits of generally prohibiting persons under 18 years old from applying RUPs justify the costs.

The 1974 Certification of Pesticide Applicators regulation has no minimum age restriction for certified applicators of restricted use pesticides (RUPs), or to persons using RUPs under their supervision. Pesticides not classified as RUPs are available for use by the general public. In contrast, EPA classifies a pesticide as RUPs if the toxicity exceeds one or more human health toxicity criteria; it is hazardous to non-target organisms or ecosystems; or if it may cause unreasonable adverse effects on human health and/or the environment without such restriction. EPA proposed a minimum age requirement for RUP use of 18 for private and commercial applicators, as well as for persons working under their direct supervision. The Department of Labor requires that workers in non-agricultural industries be at least 18 years old to perform hazardous jobs and 16 for nonagricultural employment when working with pesticides unless employed by a parent or someone standing in place of the parent. Also, the Fair Labor Standards Act establishes a minimum age of 16 for agricultural occupations deemed hazardous by the Secretary of Labor. The final rule requires a minimum age of 18 to use a RUP, with certain exceptions for persons 16 years of age working under the supervision of a private applicator who is a member of the immediate family. EPA provided this exception to alleviate the impacts to family farms.

Q. ***There is an exception to the minimum age of 18 for noncertified applicators using RUPs under the direct supervision of a private applicator who is also an immediate family member. Why doesn't the exception extend to pest operator small businesses?***

Answer:

- In the revised rule, all applicators seeking certification, whether as a private applicator (farmer) or commercial applicator (for hire), must be at least 18 years old. There is no exception to the minimum age of 18 for certified applicators.
- Applicators using restricted use pesticides under the direct supervision of a certified applicator must also be at least 18 years old, with one exception.
    - A person working under the supervision of a private applicator who is also an immediate family member, and working on a family farm can be as young at 16 and apply restricted use pesticides. This approach is partly based on the Worker Protection Standard's partial exemption for owners of agricultural establishments and their immediate family members.
- EPA did not add an exception to the minimum age for people using restricted use pesticides under the supervision of a commercial applicator, regardless of whether the supervising commercial applicator is a member of the noncertified applicator's immediate family.
- These types of restricted use pesticide applications are more likely to occur at sites where misapplication could cause harm to other people, such as to schools, homes, hospitals, parks, shopping centers and offices.

Background:
To ensure an adequate level of protection not only for the person being supervised, but also for those who live in, work at, or visit areas treated by these noncertified applicators, EPA has chosen to require that all noncertified applicators under the supervision of commercial applicators must be at least 18 years old.

EPA provided an exception to the 18-year old minimum age requirement so that persons in agriculture working under the supervision of a certified private applicator who is a member of their immediate family, under certain conditions. EPA provided this exception to alleviate the burden to "family farms." Under the Worker Protection Standard (WPS), the 2015 revisions established a minimum age for pesticide handlers (mixers, loaders and applicators) and for early-entry workers (who do work in treated areas during the restricted-entry interval under certain conditions and constraints). However, the WPS exempts owners of agricultural establishments (farms, forest, nurseries and greenhouses) and their immediate family members from many of the WPS requirements, including the minimum age requirements. The exception in the certification rule for noncertified applicators working under the direct supervision of a certified private applicator who is an immediate family member is within the scope of the WPS partial exemption.

Q. ***What are the impacts on small businesses?***

Answer:
The rule may affect over 800,000 small entities, particularly in the agricultural sector, with an impact of less than 1% of the annual value of sales or revenues, and is expected to have a negligible effect on jobs and employment. EPA has certified that the final rule will not have a significant impact on a substantial number of small entities.

Background:
EPA convened a Small Business Advocacy Review Panel on the potential revisions to the rule in 2008. As part of the review, EPA considered input from a group of Small Entity Representatives from small businesses and organizations that could be affected by the potential revisions. In the final rule, EPA estimates that it may affect over 800,000 small farms that use pesticides. However, EPA expects that about 400,000 of those farms actually use RUPs. The impact is less than 1% of the annual revenue for the average small entity.

Q. ***Would this revised certification rule have prevented the 2015 pesticide misuse incident involving methyl bromide in the Virgin Islands?***

Answer:
Several of the changes would make tragic incidents like the Virgin Islands incident far less likely to occur. Fumigants like the one used in that case could only be applied by trained and certified applicators, and certified applicators have to be specially trained or pass an exam to be renewed every 5 years. Those working under the supervision of certified applicators will receive training annually on using Restricted Use Pesticides safely.

Background:
In March 2015, a family fell gravely ill while on vacation in St. John, U.S. Virgin Islands after having been exposed to methyl bromide, a highly toxic RUP. Members of the family suffered permanent damage. In violation of the label and the law, two Terminix employees applied the outdoor, agricultural use pesticide to eradicate bugs indoors in a resort condo unit below the family's. Methyl bromide can result in serious health effects, including central nervous system and respiratory system damage. EPA banned indoor use of methyl bromide products in 1984. The previous rule required users of restricted use pesticides to be certified, but lacked specific controls for applicators using certain methods of application (such as fumigation) and any mandatory recertification and did not have training requirements for those applicators working under the direct supervision of a certified applicator.

Worker Protection Standard

Q. ***What is the Designated Representative requirement in the revised WPS? What are the issues with it?***

Answer:
Under the WPS, a worker or handler would be allowed to designate a representative who can act on behalf of the worker to request and obtain a copy of the pesticide application and hazard information required by the rule. The provision would provide workers and handlers access to appropriate pesticide-specific hazard information.

The regulated community is concerned that the requirement poses additional burdens to provide the records and, in particular, fears that the information could be misused by anti-pesticide organizations. Some commenters stated that the requirement is a violation of farmer's legal and privacy rights.

Background:
EPA established this requirement due to concerns that workers or handlers might not be able to communicate their needs in English; or understand the information without help, or they might be afraid of retaliation if they ask for it themselves. Others may have left the area because they changed jobs and don't have transportation.

Q. ***What is the Application Exclusion Zone (AEZ) in the revised WPS?***

Answer:
The "Application Exclusion Zone" or AEZ refers to the area surrounding the pesticide application equipment that must be free of all persons other than appropriately trained and equipped handlers during pesticide applications.

Q. ***What are the concerns related to this requirement?***

States, the regulated community, and pesticide manufacturers expressed their oppositions to the AEZ for logistical and economic reasons, stating that the approach is complicated because it

establishes another area to be controlled that varies by application type, and because it includes persons within the zone but not on or employed by the establishment.

States were concerned about their ability to enforce the requirement, and agricultural employers believed that the AEZ on farms and forests would be logistically difficult and could shut down parts of their operations while applications take place.

Background:
The AEZ is measured from the application equipment and the zone moves with the application equipment like a halo around the application equipment. The size varies depending on the type of application and other factors, including droplet size and height of nozzles above the planting medium. The distance from the application equipment may be zero, 25, or 100 feet. The requirement is intended to protect workers and other persons from pesticide contact or drift during application.

In the 1992 WPS regulation, agricultural employers could not allow or direct any person, other than an appropriately trained and equipped handler, to enter or remain in a "entry-restricted area" during an application in a nursery or greenhouse. There was no comparable requirement for farms and forests. In the March 2014 proposed rule, EPA solicited comments on retaining and slightly modifying the entry-restricted area for nurseries or greenhouses, and requiring them during applications on farms and in forests.

Commenters strongly opposed the entry-restricted area on farms and in forests, arguing that it would be difficult to comply with and was unnecessary. In the November 2015 final regulation, EPA took a different approach and required application exclusion zones to keep workers and other persons a certain distance away from operating pesticide application equipment – where pesticide is most likely to be – rather than from the edges of the areas being treated. Both the old and revised WPS include a requirement that the applicator must apply the pesticide in a way that does not contact workers or other persons, either directly or through drift. EPA felt it was necessary to include additional protections, because of the number of drift incidents despite the "do not contact" requirement.

Chlorpyrifos

Q. ***EPA's previous risk assessments and several consultations with EPA's FIFRA Scientific Advisory Panel (SAP) makes clear the potential for adverse neurodevelopmental outcomes to children as a result of exposure to chlorpyrifos. In October 2015, EPA proposed to revoke all tolerances because it could not determine that aggregate exposure to residues of chlorpyrifos were safe to children or the general population under the requirements of the FQPA. Do you support this decision, and if so, what basis does EPA have to allow the continued use of chlorpyrifos?***

Response:
Following a review of public comments on both the November 2015 proposal to revoke tolerances and the November 2016 notice of data availability, EPA concluded that, despite several years of study, the science addressing neurodevelopment effects remains unresolved.

Further evaluation of the science during the remaining time provided by the statute for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects from human exposures to chlorpyrifos.

Background:
The FIFRA SAP has reviewed experimental toxicology and epidemiology data, and their incorporation into risk assessment (2008, 2012, 2016), risk assessment approaches for semi-volatile pesticides (2009) and the evaluation of a chlorpyrifos-specific pharmacokinetic-pharmacodynamic (PBPK-PD) model (2011). The SAP's reports have offered numerous recommendations for additional study and sometimes conflicting advice for how the EPA should consider (or not consider) the epidemiology data regarding potential neurodevelopmental effects in conducting the EPA's registration review human health risk assessment for chlorpyrifos.

All tolerances and uses remain available at this time, and will remain available unless EPA determines differently during the course of its ongoing review. EPA has committed to completing this review by 2022.

Q. ***Section 408 (b)(2)(C) of FFDCA states that "the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children." EPA and multiple SAPs have demonstrated the use of animal toxicity data alone is not reliable in making a safety finding, so why isn't EPA at least moving forward with a decision utilizing the 10X Food Quality Protection Act (FQPA) safety factor in order to protect the most sensitive populations?***

Response:
In light of the SAP's conflicting advice on how the EPA should consider (or not consider) the epidemiology data regarding potential neurodevelopmental effects over the course of multiple panels, and following a review of public comments on both the November 2015 proposal to revoke tolerances and the November 2016 notice of data availability, the EPA concluded that, despite several years of study, the science addressing neurodevelopment effects remains unresolved.

When EPA completes its evaluation of the science around potential neurodevelopmental effects it will also address the need to retain the FQPA safety factor.

Background:
The November 2015 proposed rule for revoking all tolerances of chlorpyrifos was based on the 2014 human health risk assessment that used the 10% red blood cell acetylcholinesterase inhibition endpoint. At that time, EPA could not make a determination of 'reasonable certainty of no harm' due to risks identified from drinking water using a national-scale assessment. That

assessment included a 10X FQPA safety factor from uncertainty regarding the relationship of observed neurodevelopmental outcomes to acetylcholinesterase inhibition.

Q. ***In December 2014, EPA found unsafe drinking water contamination from chlorpyrifos as part of its risk assessment. In November 2016, EPA issued a refined drinking water assessment that still indicates potential risk to certain vulnerable watersheds. Does EPA's further reevaluation of the science around potential neurodevelopmental effects significantly impact these findings, and what would you do to address the populations where EPA has identified drinking water concerns in the meantime?***

Response:
In order to determine if there is a risk of concern for drinking water exposures, EPA must first complete its evaluation of the science around potential neurodevelopmental effects and determine an appropriate Drinking Water Level of Concern in order to determine safe levels in drinking water.

Background:
EPA completed its refined regional drinking water assessment in 2016, in order to examine estimated drinking water concentrations on a regional and/or watershed scale to pinpoint community drinking water systems where exposure to chlorpyrifos as a result of chlorpyrifos application may pose an exposure concern.

Q. ***Given that the EPA has publicly said it moved chlorpyrifos earlier in its review schedule, to 2009, in order to address the complex and cutting edge scientific issues surrounding the potential for neurodevelopmental effects to children, do you support EPA's decision not to complete the review of chlorpyrifos until 2022?***

Response:
EPA is committed to completing that review in accordance with the congressionally mandated registration review of chlorpyrifos.

Background:
EPA did move chlorpyrifos earlier in its review schedule with the intention of addressing the complex and cutting edge scientific issues surrounding the potential of neurodevelopmental effects. However, as was made apparent by the conflicting advice across SAPs for how the EPA should consider (or not consider) the epidemiology data regarding potential neurodevelopmental effects, the science addressing neurodevelopment effects remains unresolved. EPA is currently considering options for reevaluating the science around this issue, including the related epidemiology studies.

Q. ***EPA has previously stated it does not have access to the raw data from the epidemiology study used in its 2014 human health risk assessment, as well as the 2016 revised human health risk assessments supporting the proposed tolerance revocation. Moving forward with EPA's further evaluation of the science around potential neurodevelopmental effects, do you support EPA's reliance on a study without having access to the raw data, or the ability to make it available to the public?***

Response:
While lack of access to raw data does not preclude the agency from using the results of scientific studies in its decision-making, the information and analyses available to the agency must be sufficient to ensure that conclusions drawn from the study data are fully supportable for regulatory decision-making, considering the impacts these decisions may have on public health and on the regulated community.

Background:
While the EPA strives to ensure that the data underlying research it relies upon are accessible to the extent possible, it does not believe that it is appropriate to refuse to consider published studies in the absence of underlying data. EPA frequently relies on peer reviewed studies in the public literature across agency programs without possessing underlying data and the federal courts have made clear that the EPA is not required to obtain or analyze the raw data in order to rely on such studies. If EPA and other governmental agencies could not rely on published studies without conducting independent analyses of the raw data underlying them, then much relevant scientific information would become unavailable for use in setting standards to protect public health and the environment.

Q. ***Numerous stakeholders and the SAP have weighed in on possible confounding factors that could affect, influence, or produce the results observed in the epidemiology study EPA has relied on for its 2014 and 2016 human health risk assessments. How would you resolve the numerous questions around the reliability of this dataset moving forward in EPA's review?***

Response:
I would be interested in exploring additional analyses that would lead to a broader consensus on whether and how to utilize this information moving forward.

Background:
OPP has faced criticism from various points of view on its approach to evaluating and using epidemiology data, particularly in using the Columbia Children's Center for Environmental Health study for incorporation into the chlorpyrifos risk assessment. EPA has committed to continuing to evaluate the science around potential neurodevelopmental effects.

Dicamba

Q. ***What action is EPA considering to address reports of crop damage from the use of Dicamba herbicide products?***

Answer:
We continue to work with stakeholders and hope to soon have an agreement from the registrants to address the risks to allow farmers to make informed choices for seed purchase for the 2018 growing season

Background:

- EPA has lead efforts to assess and understand reported crop damage by meeting with registrants, state officials and crop protection experts to discuss possible causes of the damage and determine if additional regulatory steps or use adjustments are needed to protect crops.
- While the underlying causes of the various damage incidents are not yet clear, EPA is reviewing the current use restrictions on labels for these dicamba formulations and will rely on the best information available to inform our assessment.
- Dicamba is an active ingredient contained in certain herbicides. Herbicides containing dicamba are registered for uses in agriculture, residential areas and other sites.
- Older product registrations include uses on cotton and soybeans, but are restricted to pre-plant and post-harvest burndown applications only. The product labels for those herbicides specify that restriction. Only the new registered products may be applied over-the-top of growing soybeans and cotton.
- Late last year, EPA approved the conditional registration of three new dicamba herbicide products for use in-crop (over-top of growing crop plants) as a post-emergent application in Bollgard II XtendFlex cotton and Roundup Ready 2 Xtend soybeans, which are now available for use in the 2017 growing season:
  - DuPont FeXapan Herbicide Plus VaporGrip Technology
  - Engenia Herbicide
  - XTENDIMAX with VaporGrip Technology
- EPA limited the registration to 2 years to allow for opportunity to reassess with experience.
- Despite the conditional approval of these new dicamba products with drift reduction agents and further use restrictions set in place prior to the 2017 growing season, some states are reporting high numbers of dicamba complaints. By late August, EPA had been made aware of reports of thousands of complaints made to state agencies. Initial reports came from Arkansas, Missouri, Mississippi, and Tennessee, and then expanded to northern states (Iowa, Nebraska, and Kansas) as the growing/use season proceeded.
- Both physical drift and volatilization of dicamba from the target application site have been reported.
- The underlying causes of the various damage reports are still being investigated.

Glyphosate

Q. ***What is the reason for the repeated delays of EPA's glyphosate risk assessment?***

Answer:
EPA delayed its risk assessment to 2015 in order to respond to a petition from the Natural Resource Defense Council (NRDC); however, in the meantime, the International Agency for Research on Cancer (IARC) released its conclusion that glyphosate was a probable cancer agent in 2015. As a result, EPA delayed its risk assessment again in order to review IARC's report and conduct its own comprehensive evaluation.

Background:

- In 2016, EPA held a FIFRA Scientific Advisory Panel (SAP) meeting to discuss the carcinogenic potential of glyphosate. Currently, EPA is reviewing and considering the SAP's recommendations.
- EPA was originally scheduled to release its risk assessment in 2014. This was delayed due to receipt of a petition from the NRDC to curb the use of glyphosate, on the grounds that it was killing milkweed, a key resource for the monarch butterfly.

Q. ***What is EPA's current schedule for the review of glyphosate?***

Answer:
The draft human health and ecological risk assessments for glyphosate will be completed in late 2017 and published for public comment in early 2018.

Background:
EPA is currently evaluating glyphosate as part of registration review and will open a 60-day public comment period for its risk assessments. The Proposed Interim Decision (PID) is scheduled to publish in 2019, which would weigh the risks and benefits of the use of glyphosate and outline proposed measures to address identified risk (i.e., risk mitigation measures), if needed. After public comments on the PID are reviewed, EPA will issue an Interim and implement any necessary label changes. EPA's registration review decision will remain interim until the agency completes a national-level endangered species assessment. If EPA determines that glyphosate may affect listed species, EPA will initiate consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service. EPA is scheduled to complete endangered species effects determinations and initiate consultation with the Services for glyphosate by 2020.

Dietary Exposures

Q. ***Is glyphosate used on genetically modified organisms and is it safe to consume GMOs with residues of glyphosate?***

Answer:
Glyphosate is used on a variety of crops, including certain genetically engineered plants (also known as GMOs). Uses of glyphosate on genetically engineered plants are assessed for risks to human health when they are first added to the pesticide label, and EPA determined that residues of glyphosate from genetically engineered plants are safe for consumers provided the use complies with the existing labels.

Q. ***Given recent reports that glyphosate was detected in food/drink that children regularly consume, should parents be especially concerned?***

Answer:
Due to its widespread use, trace amounts of glyphosate residues may be found in various food and beverage commodities. However, EPA is required under the law to be protective of children

in its risk assessment process and has not identified any concerns for children in its most recent 2012 human health risk assessment

Q. *Has glyphosate been detected in breast milk?*

Answer:
EPA is not aware of any peer-reviewed studies reporting glyphosate residues being detected in human milk.

Background:
The 2012 risk assessment was conducted in support of the registration of new uses on several crops.

Food and food ingredients derived from genetically engineered plants are primarily regulated by the Food and Drug Administration (FDA) and must adhere to the same safety requirements that apply to food and food ingredients derived from traditionally bred plants. EPA has a statutory requirement to evaluate all pesticides and ensure that there is a "reasonable certainty of no harm" when pesticides are applied according to the label, which includes application to genetically engineered plants. Plants genetically engineered to be tolerant to glyphosate include corn, soybean, sugar beet, cotton, wheat, alfalfa, and canola.

Moms Across America, an advocacy group, analyzed 10 human milk samples and claimed glyphosate was detected in a subset of these samples (3 samples); however, EPA identified several methodological issues that would prevent the Agency from using the results. Subsequently, Washington State University scientists published data in a peer-reviewed journal demonstrating that glyphosate was not detected in 41 human milk samples. These analyses were conducted both in Monsanto laboratories and independently verified at Covance laboratories, which is not affiliated with Monsanto or Washington State University. The EPA has obtained 39 human milk samples from the National Institutes of Health (NIH) to analyze for the presence of glyphosate and the results will be included in the Registration Review docket for glyphosate with the preliminary human health and ecological risk assessments.

Q. *The International Agency on the Research for Cancer (IARC) determined in 2015 that glyphosate is likely to cause cancer. What is EPA's position on this and how is this information being considered?*

Answer:
EPA performs its own independent evaluation of available data to determine the carcinogenic potential of a pesticide, which includes all available animal carcinogenicity, mutagenicity, and epidemiology data. Following IARC's classification of glyphosate as "probably carcinogenic to humans (Group 2A)," EPA conducted a comprehensive analysis of all the available data to inform the human carcinogenic potential of glyphosate and concluded glyphosate is "not likely to be carcinogenic to humans at doses relevant for human health risk assessment."
In December 2016, EPA's evaluation was reviewed by the FIFRA Scientific Advisory Panel (SAP). The SAP released a report in March 2017 and EPA will respond to this report as part of its draft human health risk assessment to support Registration Review.

Q. ***Why does EPA disagree with the IARC assessment? How can EPA and IARC come to different conclusions about glyphosate's ability to cause cancer?***

Answer:
EPA's cancer classification for glyphosate is based on a weight of evidence evaluation in accordance with the Agency's 2005 Guideline for Carcinogen Risk Assessment. The dataset considered by EPA included studies submitted for registration of glyphosate, as well as studies identified in the open literature as part of a systematic review. IARC only considers data that has been published or accepted for publication in the openly available scientific literature. As a result, IARC only considered a subset of the cancer studies included in the EPA evaluation.

Background:
IARC's conclusion is inconsistent with the international community whereas EPA's conclusion is consistent other countries and regulatory authorities including Canada, Australia, European Food Safety Authority (EFSA), Germany, The Joint FAO/WHO Meeting on Pesticide Residues (JMPR), European Chemicals Agency (ECHA), Japan, New Zealand

Q. ***It was recently reported that Aaron Blair, who chaired the IARC deliberations for glyphosate, and who is also co-author of the Agricultural Health Study (AHS), did not disclose unpublished findings for glyphosate from the AHS that would have informed IARC's glyphosate cancer classification. The data strongly suggested that glyphosate did not cause cancer. Did EPA have access to this data? Would it have an impact on EPA's cancer evaluation?***

Answer:
EPA did not have access to recent unpublished data for glyphosate from the Agricultural Health Study (AHS) at the time of its 2016 cancer evaluation. EPA noted that the data in this unpublished journal manuscript support no association between glyphosate exposure and lymphoma risk, which is consistent with the EPA's conclusion that glyphosate is "not likely to be carcinogenic to humans at doses relevant for human health risk assessment." These findings have not been peer-reviewed; however, EPA anticipates a new evaluation from AHS regarding glyphosate exposure and lymphoma risk that will be published in a peer-reviewed journal in the coming months.

Question:
As part of ongoing litigation involving Monsanto, it has also been reported that EPA employees (specifically Jess Rowland) colluded with Monsanto to maintain that glyphosate does not cause cancer. What is EPA's response to these reports?

Answer:
There was no collusion between EPA staff and representatives of Monsanto. EPA employees maintain a high level of ethical conduct to maintain the public trust.

Background:
When a chemical is under review, EPA maintains a dialogue with the pesticide registrants in order to obtain information needed for risk assessment or risk management. EPA routinely meets

with other interested stakeholders to discuss chemicals under review, including environmental groups and activist groups. Reports of alleged conversations between EPA officials and a chemical registrant was taken out of context are not evidence of collusion.

Q. ***Is it true that glyphosate is linked to Parkinson's disease and non-Hodgkin's lymphoma?***

Answer:
No, the available scientific data, including the previously undisclosed glyphosate data from the Agricultural Health Study, do not support a cause and effect relationship between exposure to glyphosate and Parkinson's or non-Hodgkin's lymphoma.

Background:
If, at any time, reliable data are available that suggest unexpected risks due to glyphosate exposure, the agency will ensure the data are evaluated and move quickly to take the appropriate regulatory actions, when necessary.

Q. ***Why is California listing glyphosate as a cancer agent under Proposition 65?***

Answer:
IARC has been identified as a designated authoritative body under Proposition 65; therefore, given IARC's classification of "probably carcinogenic to humans", glyphosate has been listed in California.

Background
As of July 2017, the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is listing glyphosate as an agent known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Proposition 65 requires California to publish (at least) yearly a list of chemicals known to the state to cause cancer or birth defects or reproductive toxicity. One of the ways for a chemical to be added to the Proposition 65 list is if an "authoritative body" has identified it as an agent causing cancer.

Q. ***Is glyphosate an endocrine disruptor?***

Answer:
Based on all available information, EPA concluded using a weight of evidence approach that the existing data do not indicate that glyphosate has the potential to interact with the estrogen, androgen, or thyroid signaling pathways.

Background:
Glyphosate has undergone Tier I screening under EPA's Endocrine Disruptor Screening Program (EDSP) and was not recommended under EDSP for additional testing.

Q. ***There's widespread weed resistance to glyphosate. What is EPA doing about weed resistance?***

Answer:
Implementing measures that promote proper weed resistance management is a high priority for the agency. In 2016, EPA published for public comment draft weed resistance management guidance for herbicide labeling, education, training, and stewardship. Final guidance will be issued later this year.

Background:
EPA is working actively with a wide range of stakeholders, including USDA and the Weed Science Society and America, and will continue to expand work with affected stakeholders to implement this new weed resistance management guidance.

Q. ***Glyphosate kills milkweed, a key resource for the monarch butterfly. What is EPA doing to protect the monarch butterfly?***

Answer:
EPA believes that monarch conservation is important and in 2015 published and took public comment on a risk management approach intended to identify options to protect the monarch butterfly. EPA sought information relating to the impact of herbicides on milkweed and encouraged stakeholders to submit information on existing practices that promote the co-occurrence of agricultural production with milkweed maintenance. EPA has evaluated the comments received and will issue a revised risk management approach, outlining a multi-pronged strategy for managing risks to monarch butterflies from the use of herbicides.

Background:
On June 24, 2015, EPA published the document titled "Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly"

Glyphosate is an herbicide and is registered for use to treat milkweed, which is considered a weed in agricultural settings. Glyphosate, like all similar herbicides, may indirectly affect the monarch butterfly by affecting milkweed resources. However, it is not known to what extent herbicide use in general may contribute to the decline of the monarch butterfly. EPA believes that various factors are contributing to the decline of the monarch butterfly, including loss of overwintering habitat in the Sierra Madre mountains of Mexico.

Q. ***Recently, a collection of 20,000 documents from several sources, including EPA, were published online. The collection, with documents dating back to the 1920s, was termed the "Poison Papers." Environmental activists allege that the documents contain correspondence which show that Monsanto doctored scientific studies in order for regulatory agencies to view glyphosate in a favorable light. What is EPA's response to this?***

Answer:
EPA is aware of the "Poison Papers" and has not had a chance to review all the documents, and therefore cannot comment on the allegations.

Background:

- EPA is always concerned when there are suspected fraudulent studies. However, it is hard to know exactly what is in this tremendous collection of documents.
- EPA will continue to rely on the best scientific data available for its evaluation of glyphosate. The glyphosate dataset is composed of thousands of studies and consists of data from a variety of sources, including other pesticide companies, academia, and published scientific literature.
- We look closely at every study to determine whether the results are scientifically sound. Our analysis gives greater weight to high quality and well documented studies and those findings confirmed by multiple sources.

Organophosphates

Q. ***What is the agency's plan for completing its re-evaluation of the organophosphates (OPs)?***

Answer:
EPA has released two Proposed Interim Decisions as well as two Interim Decisions for the organophosphates. The rest of the decisions are scheduled for completion by 2022.

Between September 2015 and May 2017, the agency released preliminary risk assessments for 18 of the organophosphates going through registration review. For 6 of the organophosphates, the preliminary risk assessments are still in progress and/or pending release.

Background:
In making a risk management decision under FIFRA (for occupational and ecological risks), the agency takes into account the economic, social, and environmental costs and benefits of the use of any pesticide. However, under FQPA (for dietary and residential risks), the agency must meet safety standards regardless of other factors. The Proposed Interim Decisions will outline proposed measures to lessen any unreasonable risk.

After the 60-day public comment periods for the preliminary risk assessments closes, the agency evaluates the comments received and considers any potential risk management options for the pesticides. After public comments on the Proposed Interim Decision are evaluated, EPA will issue an Interim Decision for each organophosphate. Implementation of any labeling changes for the organophosphates would occur subsequently. EPA must also complete the cumulative risk assessment for the organophosphates

Q. ***In nearly all of the draft OP human health risk assessments released to date, the agency has included an FQPA 10X safety factor for neurodevelopmental effects, largely based on epidemiological data. Is the use of epidemiological data for risk assessment purposes typical?***

Q. Do you support the use of epidemiological data for risk assessment purposes?

Q. Do you support the use of the FQPA 10x safety factor in the OP risk assessments?

Answer:
The agency plans to release for public comment a petition from CropLife America asking the agency to halt regulatory decisions that use epidemiological studies that do not meet certain data quality standards and that are not integrated into the health risk assessment in a transparent, well defined manner. EPA will consider the comments before responding to the petition and as it moves forward with current human health risk assessments. [Note: this may happen before the hearing.]

Under FQPA (1996), the 10X factor is required unless reliable data support the use of a different factor. In 2014, EPA determined that reliable data were not available to reduce the FQPA 10X factor. EPA recently released the *Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides*, which describes how EPA identifies and evaluates epidemiology studies and considers these studies in combination with laboratory studies.

Background:
The agency has conducted a thorough review of the scientific literature on the potential for exposure organophosphate pesticides to result in adverse effects on the developing brain. Many of these studies were also reviewed by three separate FIFRA Scientific Advisory Panels. The FIFRA SAP has questioned the agency's historical approach of conducting risk assessments for these pesticides as not being sufficiently health protective. EPA continues to evaluate emerging scientific evidence. Moreover, EPA is actively engaging the scientific community in order to build consensus on the appropriate approach for the human health risk assessments.

Q. *CropLife America submitted a petition to the agency in November 2016. The petition asks the agency to "halt regulatory decisions that are highly influenced/determined by results of epidemiological studies that do not meet well-defined data quality standards and that are not integrated into the health risk assessment in a transparent, well defined manner." The agency has remained silent on this petition. How will you move the response to the petition forward?*

Answer:
The agency plans to release the petition for a 30-day public comment period and will consider the comments before responding to the petition and as it moves forward with current human health risk assessments. [Note: this may happen before the hearing.]

Background:
In December 2016, EPA completed and subsequently released the *Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides*, which describes how EPA identifies and evaluates epidemiology studies and considers these studies in combination with laboratory studies.

EPA has made the petition available to the public, via the docket for various chemicals going through registration review, but hasn't taken comment or responded to it yet.

Q. ***Recent assessments on chlorpyrifos, malathion and diazinon, three organophosphates, indicate that these chemicals are harmful to many threatened and endangered species. What will you do to mitigate the risk to these threatened and endangered species?***

Answer:
EPA released its Biological Evaluations for chlorpyrifos, malathion and diazinon in January 2017 and expects to receive draft Biological Opinions from the Fish and Wildlife Services and National Marine Fisheries Service (referred to as The Services) for these three pesticides. The agency anticipates releasing the Draft Biological Opinions for public comment before the final Biological Opinions are issued. Once the agency reviews the Services' final Biological Opinions and any public comments, the agency will consider the reasonable and prudent measures and reasonable and prudent alternatives identified by the Services.

Q. ***How does EPA plan to respond to requests from industry to retract the Biological Evaluations for the 3 OPs given that they were based on "flawed scientific methods?"***

Answer:
The methods used to evaluate possible effects to Threatened and Endangered species from potential exposure to malathion, diazinon, and chlorpyrifos were developed jointly with Fish and Wildlife Services and National Marine Fisheries Service (referred to as The Services). The methods are intended to be interim, and work is ongoing to refine and streamline these methods based on feedback and comments received from external stakeholders.

Background:
The Biological Evaluations (BEs) are the first steps in the overall endangered species assessment consultation process. The draft Biological Opinions, which are based on the BEs, are currently being developed by the Services. Once the draft Biological Opinions have been reviewed and subjected to public comment, EPA will determine the most appropriate course of action.

Q. ***The registration review of the OPs is proceeding slowly, especially given the risks of concern identified in the preliminary risk assessments. Why is the OP review so lengthy and complex, and what will you do to move it along?***

Answer:
EPA bases its decisions on a thorough evaluation of the best available scientific information. As the preliminary risk assessment for the OPs have been released to the public, registrants have responded to concerns by generating additional data. The agency intends to consider the additional data and determine whether additional refinements to the risk assessments are necessary. The agency's mitigation decisions for the OPs will depend on the risks identified for each chemical and, when appropriate under FIFRA, consideration of the benefits. The agency is committed to completing registration review for the OPs by 2022.

Endangered Species Act

Q*: Is EPA proposing any changes to its plans for assessing the risk of pesticides for endangered species?*

Answer:
The current schedule for completing the initial set of biological evaluations has not changed.

- EPA released the biological evaluations for chlorpyrifos, diazinon, and malathion in January 2017, and their biological opinions are scheduled to be completed at the end of 2017.
- The Services are currently scheduled to complete biological opinions for methomyl and carbaryl by December 2018.
- EPA is currently scheduled to complete effects determinations and initiate consultation for atrazine, simazine, propazine, and glyphosate by 2020.

EPA, National Marine Fisheries Service and Fish and Wildlife Services (the Services) are currently involved in discussions exploring possible options for streamlining the interim methods and process we have developed based on the recommendations of the National Academy of Sciences in its April 2013 report. EPA is also currently considering a request that the first three biological evaluations be remanded to allow for further refinement of the interim process.

Background:
The NAS recommendations for assessing risk from pesticide exposure to threatened and endangered species involves a 3-step process that integrates ecological risk assessment methods with ESA consultations. EPA, NMFS, FWS and USDA held several workshops to develop those interim methods, which were intended to be part of an iterative process that continues to evolve as EPA and the Services gain experience with the process. EPA used those interim methods in the biological evaluations for chlorpyrifos, diazinon, and malathion, which were released in January 2017. On April 13, 2017, registrants for these pesticides sent letters to the political leadership of the EPA and the Services requesting the EPA withdraw the BEs, the Services stop work on their BiOps, and modify the settlement agreements to allow more time to complete consultation. The EPA is considering the request.

PRIA4

Q: *Does the FY 2018 budget provide the staff and resources needed to adequately assess the risk of pesticides for these species?*

Answer:
Yes, the FY 18 President's budget provides the staff and resources needed to adequately assess the risk of pesticides to endangered species.

Background:
Currently, registration user fees can cover a portion of the costs associated with the assessment of risks to endangered species. If PRIA 4 passes, it will also have language that will explicitly cover allowing the use of maintenance fees funding to cover the costs of endangered species activities; although currently under FIFRA, nothing prevents the EPA from using maintenance fees for endangered species activities.

Q. ***What is the current status of PRIA 4?***

Answer:
The reauthorization of the Pesticide Registration Improvement Act (PRIA 4) passed in the House (H.R. 1029) in March 2017 as a 7-year extension with two 5% fee increases in that time frame. The amended bill passed the Senate Agriculture Committee as a 3-year authorization with no fee increases and has not gone to vote in the Senate due to a hold.

Q. ***Do you support the passage of PRIA 4 and what would be the impact on EPA and pesticide registrations if PRIA 4 does not pass into law?***

Answer:
Yes, I support the passage of PRIA 4. It's not passed by September 30, 2017, when PRIA 3 sunsets, pesticide applications received after October 1, 2017, will no longer be subject to decision time periods; fees would be reduced in the first year by 40% below 2017 levels and by 70% in the second year and then would be terminated. Loss of an estimated $17 million a year in PRIA fees and $31 million a year in maintenance fees would impact the program's ability to meet its statutory responsibilities to register and re-evaluate pesticides.

Background:
- EPA has provided technical assistance to the House, the Senate, Congressional Budget Office, Office of Management and Budget, and a coalition of pesticides stakeholders supporting the bill.
- PRIA establishes a fee for service framework that charges applicants based on the type and complexity of the activity requested. It permits market access to pesticides within predictable time frames, benefitting both the pesticide and agricultural industries, while safeguarding the environment and human health. Growers and other pesticide users can thus rely on innovative products to be available when pest pressures occur, including existing and emerging public health pests.
- PRIA 4 would provide continued funding for the statutorily required reevaluation of existing pesticides, which is important to both the crop protection industry and the environmental and public health community. The legislation provides incentives for actions supporting reduced risk pesticides and funds are made available to advance worker protection and pesticide applicator safety training.
- PRIA 4 brings together broad coalition of stakeholder groups representing seven pesticide industry trade groups and two non-governmental organizations, which has paved the way to expedited approval processes in Congress to pass the original law and its amendments to extend.

- The fees fund a portion of the EPA's pesticides registration and registration review activities and help support staff and other expenses related to pesticides registration and registration review.
- PRIA allows partial fee waivers for small businesses and exempts federal and state government entities from fee requirements. Applications supported by the IR-4 Project, a USDA-funded program which supports the availability of pest management tools for growers of minor use crops, are likewise exempt from fee requirements.
- Since PRIA initially became law in March 2004, the EPA has approved over 20,000 pesticide applications, meeting or beating mandated due dates for over 98% of those actions.

Neonicotinoids

Q. ***With all the available studies describing effects of neonicotinoids on bees, why can't we definitively determine whether neonicotinoids are responsible for declines in bee populations?***

Answer:
The prevailing understanding among scientists in EPA, USDA, the National Academy of Sciences, and the global scientific and regulatory community is that the general declining health of honey bees is related to complex interactions among multiple stressors*. Precisely isolating the role of one of these stressors in overall declines in honey bee health has been a challenge.

Background:
Multiple stressors*: pathogens (viral, bacterial and fungal diseases), pests (*e.g.*, Varroa mite), poor nutrition (*e.g.*, loss of foraging habitat), bee management practices (*e.g.*, long migratory routes to support pollination services), lack of genetic diversity, and pesticide exposure.

While many studies have been published on the effects of neonicotinoids on honey bees, the quality and design of these studies differ widely, as does their overall conclusions. EPA has applied a consistent process, using reproducible study designs and conclusions for evaluating the potential effects of pesticides on bees that has been vetted through numerous FIFRA Scientific Advisory Panels. The process being used by EPA to evaluate potential risks to bees is a tiered approach that ultimately examines the potential effects on honey bee colonies under increasingly realistic use conditions, with a concordance of information across multiple studies and study types.

Q. ***What action is the EPA taking to protect bees from neonicotinoid pesticides?***

Answer:
In 2013, EPA imposed labelling requirements for neonicotinoid insecticides prohibiting the use of certain neonicotinoids when managed honey bee colonies are present. These requirements are intended to reduce acute exposure to managed honey bee colonies. In January 2017, EPA issued a policy* to protect bees from foliar applications of acutely toxic pesticides while bees are under contract to provide pollination services. The Policy provides flexibility that balances pollinator

protection with crop production, and recommends that states and tribes develop pollinator protection plans and best management practices to protect bees.

Background:
**Policy to Mitigate the Acute Risk to Bees from Pesticide Products*
EPA has been working aggressively to protect bees and other pollinators from pesticide exposure, developing and implementing new policies while it continues to refine its methods and assess risks to bees. EPA is also continuing its registration review, and will follow its statutory responsibility to consider both risks and benefits in proposing and determining a regulatory path for the neonicotinoid pesticides.

Q. *What action is EPA taking to address bee kill incidents resulting from dust-off from seed treatment applications?*

Answer:
EPA has relied on practical, management measures* to reduce potential exposure from drift of abraded seed coat dust (dust-off) during seed planting. EPA continues to work with stakeholders to explore additional opportunities to reduce drift from dust generated during the planting of pesticide-treated seed.

Background
*Management measures: Development of a treated seed stewardship manual by the American Seed Trade Association; Development of alternative fluency agents to reduce the quantity of dust generated during planting: Improved design guidelines issued by the International Organization of Standards for agricultural planting equipment to reduce seed dust

EPA has identified that drift of abraded seed coat dust (dust-off) during seed planting operations is a potential route of pesticide exposure for pollinators. However, the extent to which dust-off occurs can vary widely due to seed quality, seeding equipment, fluency agents and weather. Given these multiple sources of variability, it is difficult to develop a suitable model for evaluating such exposure.

EPA is a member of the Corn Dust Research Consortium, a public-private partnership that has researched this potential route of exposure to bees and has in turn developed recommendations for further reducing exposure.

Q. *Why hasn't the EPA banned neonicotinoids similar to what has been done in Europe or what is planned in Canada?*

Answer:
At the time of the European Food Safety Authority (EFSA) assessment of neonicotinoids, EPA didn't have sufficient data to indicate uses would fail to meet the FIFRA standard. Also, at that time, EPA was developing its pollinator risk assessment framework along with identifying data needed to inform that framework. New pollinator data has since come in and as a result EPAs assessment differs from EFSA's, because it incorporates the new data reflecting how the state of the science has progressed between 2013 and now. Canada's recent proposed measures have

been based on risk to aquatic species (not bees). EPA plans to release its remaining assessments of risk to aquatic species in September 2017.

Background:
The EFSA assessed the available studies for the neonicotinoids and their impact on bees. Based on the conclusions from these studies in 2013, it suspended certain uses of clothianidin, thiamethoxam, and imidacloprid in the EU. As a result of the uncertainty, EFSA temporarily suspended the marketing of treated seed with neonicotinoids until a more thorough analysis could be completed to address uncertainties.

EPA is currently in the process of reviewing these data and incorporating them into its updated pollinator assessment, planned for 2018. EPA has been cooperating with Canada's Pest Management Regulatory Agency (PMRA) in further developing the science of pesticide risk to pollinators. Canada's recent proposed measures have been based on assessments of risk to aquatic species. EPA plans to release its remaining assessments of risk to aquatic species in September 2017.

Q. ***What is EPA's plan for completing its review of the neonicotinoids?***

Answer:
EPA has completed preliminary pollinator risk assessments for all four of the neonicotinoid insecticides. Updated pollinator assessments for all four compounds will be issued in 2018. EPA intends to complete draft risk assessments for human health and other non-pollinator ecological taxa, as well as benefits assessments, for all four active ingredients by September 2017

Background:
After public comment is received on these assessments, EPA will evaluate the comments received, consider the risks and benefits of the neonicotinoid pesticides, and develop appropriate risk management options for these insecticides. All proposed risk management measures are released for public comment before they are finalized.

Q. ***Does the EPA plan to assess the neonicotinoids for risk to pollinators other than honey bees?***

Answer:
EPA's bee risk assessment framework uses the honey bee as the representative (surrogate) species for all bees due to well-established test methods for honey bees. Additional data will be evaluated on bumble bees and other bee species, and characterized in EPA's final pollinator assessments planned in 2018.

Background:
In contrast to other bee species, the honey bee's ready availability, the relative ease in which it can be reared, and its ability to tolerate testing conditions makes it a good test species. These factors contribute to more reliable data on which to base decisions. As part of the preliminary risk analyses for the neonicotinoids, EPA reviewed the available data with other bee species and

found that, at the individual-level, the honey bee appears to be a good surrogate for other bee species.

Q. ***What will happen to growers if neonicotinoid pesticides are banned? Will they suffer significant economic impact?***

Answer:
The neonicotinoids are cost effective and have been incorporated into many Integrated Pest Management (IPM) programs developed by agricultural research and extension programs. These chemicals contribute substantially to the economy and serve an important role in IPM.

Background:
In many cropping systems neonicotinoids serve an important role in IPM because they are broad-spectrum and systemic, which serves to reduce the use of multiple other insecticides and the frequency of insecticide applications. In certain cases, such as citrus in Florida, the need for the neonicotinoids to aid in addressing citrus greening, has been critical. As EPA continues its reevaluation of this class of compounds, we will be assessing the benefits that these products have in meeting pest control needs.

EPA is conducting benefits assessments of the impacts of potential ways to address risks for certain neonicotinoid uses, *i.e.*, those uses identified as posing risks to bees. These benefits assessments will identify and describe the utility of the neonicotinoids, and the likely alternative insecticides, along with the impacts on growers if they were forced to use these alternatives in lieu of neonicotinoids on certain crops (cotton, citrus, and cucurbits). When released, the assessments will be made available for public comment.

Atrazine

Q. ***Is EPA aware of the published studies in scientific literature linking atrazine exposure to cancer, birth defects and other health outcomes?***

Answer:
The Agency is aware of some published literature on atrazine and possible associations with cancer, birth defects, and other health outcomes, and continues to actively monitor and consider these types of studies as a part of the registration review process.

Q. ***Why has it not taken action based on these findings?***

Answer:
Over the years we have consulted the FIFRA Scientific Advisory Panel (SAP) several times on atrazine and human health issues, and the SAP has largely been supportive of EPA's approach. After EPA completes its human health risk assessment for atrazine, EPA will consider whether action is necessary to address human health risks.

Background:
The human health risk assessment for atrazine evaluates the safety of pesticides. EPA uses a weight-of-evidence approach that incorporates consideration of all relevant, robust, and scientifically-sound information, including published literature, laboratory studies required by EPA to obtain or maintain registration, and information submitted by the public.

Q. *Why does EPA's Office of Pesticide Programs and Office of Water have such different regulatory limits for atrazine in drinking water?*

Answer:
The two offices operate under different governing statutes and accomplish the goal of protecting drinking water in different ways.

Background:
The Office of Pesticide Programs sets and enforces requirements and restrictions on pesticide use to ensure that each pesticide does not cause unreasonable adverse effects on human health or the environment, including drinking water. The Office of Water regulates drinking water more broadly by establishing and enforcing drinking water standards that limit the level of drinking water contaminants, including pesticides, and by requiring regular monitoring to ensure that the standards are being met.

Consistent with EPA's mission to protect human health and the environment, EPA's Office of Pesticide Programs and Office of Water both contribute to protecting drinking water resources in the United States. The two offices operate under different governing statutes and accomplish the goal of protecting drinking water in different ways. The Office of Pesticide Programs is updating its drinking water and human health risk assessment based on a comprehensive review of the newest scientific data available. This information will be available to the Office of Water when it reassesses regulatory limits for atrazine in water.

Q. *Why is atrazine registered in the U.S. when it is cancelled in EU?*

Answer:
EPA's approach to pesticide regulation is based on U.S. federal law, which requires a process that considers not only the pesticide's specific hazard (i.e., toxicity) but also the risk it may pose based on both hazard and exposure (risk = hazard x exposure). The EU's approach treats all pesticides alike, regardless of how toxic different pesticides may be or whether it poses a risk.

Background:
The E.U. has established a specific limit (0.1 ppb) for any pesticide in water, regardless of the level of risk.

The E.U. banned atrazine because of monitoring data showing that levels of atrazine might exceed the European legal limit of 0.1 ppb. EPA will permit a level of a particular pesticide to be present, depending on the degree of risk posed by a pesticide. This is the model upon which many countries base their own pesticide regulations.

Q: ***The EPA's Final Work Plan (2013) lists the estimated date for publication of a Registration Review Decision on Atrazine in 2016. Why has it not been released yet?***

Answer:
The ecological risk assessment was released in 2016. However, the human health risk assessment was delayed to allow for incorporation of data from a physiologically based pharmacokinetic (PBPK) model and to allow for a peer review of the model and the risk assessment approach.

Background:
EPA expects to release the human health risk assessment for atrazine in 2018 and issue a decision in 2019.

Q: ***EPA's 2016 ecological assessment showed a number of risks to the nation's water and ecological well-being. Is EPA cancelling atrazine or requiring rate reductions or any other mitigation?***

Answer:
No mitigation or changes to atrazine registrations will occur until the Agency completes its review of the public comments on the ecological assessment, completes and takes public comment on the human health risk assessment, and conducts a benefit assessment that weighs the economic costs against the environmental benefits of any possible risk mitigation, as required by FIFRA.

Background:
Based on the results of the risk assessment, aquatic plant communities are affected in many areas where atrazine use is heaviest, and there is potential chronic risk to fish, amphibians, aquatic, mammals, birds, reptiles and plants.

The 2016 ecological risk assessment reflects updated science, uses geographically explicit modeling and available water monitoring data, and incorporates the Scientific Advisory Panel (SAP) recommendations over the past decade. The findings of this risk assessment present the preliminary ecological risks associated with atrazine, and will be relied on, along with information about the benefits of atrazine, for the Registration Review decision.

The Agency received over 50,000 comments on the 2016 atrazine ecological risk assessment. Many commenters expressed the importance of atrazine use for farmers and foresters, citing improved yields, low cost, reduced need for tillage resulting in reduced erosion, effective weed control, and its utility in resistance management. The Agency anticipates publication of an Interim Registration Review Decision for public comment in 2019.

Q: ***What is the EPA conclusion regarding whether atrazine has detrimental effects on amphibians?***

Answer:
In EPA's draft ecological risk assessment, published for public comment in June 2016, the Agency concluded in a weight-of-evidence analysis that there is a potential for chronic risk to

amphibians. The agency is now considering comments submitted in response to the draft ecological risk assessment.

Background:
EPA's conclusion was based on a comparison of atrazine concentrations that resulted in effects on growth, reproduction and survival of amphibians in the scientific literature to measured and predicted surface water concentrations.

Q. ***How is EPA protecting endangered species from atrazine exposure?***

Answer:
By December 2020, the agency intends to complete a nationwide endangered species effects determination for the triazine herbicides, which includes atrazine. After completion of that effects determination, if necessary, the agency will initiate consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service, as required by the Endangered Species Act.

OFFICE OF POLLUTION PREVENTION AND TOXICS (OPPT)

TSCA Implementation Activities

Q: ***The 2016 amendments to TSCA created significant new obligations for the EPA and OCSPP, in addition to many prior responsibilities. What are your views on how implementation of the law has gone thus far, and what changes in direction do you foresee, if any?***

Answer:
I commend EPA for working so quickly and efficiently to implement the many provisions of TSCA, as amended. OCSPP was able to finalize all the key framework rules on time, and completed a host of other accomplishments on time or, in some cases, ahead of schedule. I look forward to the challenges that lay ahead, including prioritizing high- and low-priority substances, conducting risk evaluations consistent with the law and best available science, and ensuring that EPA delivers on TSCA's promise for increased chemical safety and marketplace certainty.

Background:
The EPA will continue to seek input from stakeholders on critical implementation elements of TSCA as amended. Since June 2016, EPA has held an unprecedented number of public meetings seeking input from affected entities. Moving forward EPA will focus on continuing to reduce review times and seeking additional feedback through a public meeting for the new chemicals program; providing additional opportunities on and finalizing a process for identifying candidate chemicals and information needs prior to prioritization; working towards designating 20 High-Priority and 20 Low-Priority chemicals by the end of 2019; issuing "Problem Formulation" documents that further refining the "Scope" documents published on June 22, 2017; issuing draft risk evaluations for the first 10 chemicals under review and taking public comment; proposing and finalizing a rule to partially defray implementation costs; implementing the reporting requirements of TSCA, as amended, to determine whether a chemical is active or inactive in commerce; developing a Strategic Plan for advancing the use of non-animal testing; proposing and finalizing a rule to help inform future version of the Mercury Inventory; and proposing and finalizing rulemaking to address exposures from persistent and bio-accumulative chemicals.

TSCA Framework Rules: Active/Inactive Inventory Rule

Q: ***What value do you see in the information gained from the reporting requirements of the active/inactive inventory rule?***

Answer:
After the reporting period is complete, EPA will then designate all chemical substances on the TSCA Inventory as either active or inactive. The inventory designations will be helpful, from an exposure perspective, to inform the Agency's subsequent identification of existing chemicals for prioritization and potentially further evaluation.

Background:
TSCA requires EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either "active" or "inactive" in U.S. commerce. To accomplish that, EPA finalized a

rule on June 22, 2017 requiring industry reporting of chemicals manufactured (including imported) or processed in the U.S. over the past 10 years, ending on June 21, 2016. August 11 marked the start of a 180 reporting period, to end February 7, 2018, for manufacturers and importers to notify the Agency of the status of their chemicals. All processors of chemicals also have an opportunity to report, and may do so by October 5, 2018. This reporting will be used to identify which chemical substances on the TSCA Inventory are active in U.S. commerce and will help inform the prioritization of chemicals for risk evaluation. Additionally, active and inactive designations for each chemical substance will be included as part of the Agency's regular publications of the TSCA Inventory. EPA will be hosting webinars to assist submitters this fall. Further details will be posted.

Prioritization Rule

Q: ***Are you aware that a number of lawsuits have been brought against the recently finalized Prioritization rule? Does this concern you? Why or why not?***

Answer:
Yes, there have been three lawsuits brought against the Prioritization Rule to date. I am not aware of the underlying basis of the litigation, so it is difficult to comment further.

Background:
The Agency is currently working to consolidate the petitions in a single circuit, because they are currently in 3 different courts. The process will then go as follows: First the Agency will submit the petitions filed and served on the Agency to the Judicial Panel on Multidistrict Litigation. 28 U.S.C. § 2112(a)(1). The Panel then randomly selects a court from among those where petitions were filed in which all cases will be consolidated and the agency will file the record. Id. § 2112(a)(3).

Organizations suing: Safer chemicals healthy families; Alaska community action on toxics; Environmental health strategy center; Environmental working group; Learning Disabilities Association of America; Sierra club; Union of concerned scientists; United steel, paper and forestry, Rubber, manufacturing, energy, Allied industrial and service workers international union, AFLCIO/CLC; We Act for Environmental Justice; Asbestos Disease Awareness Organization; Vermont Public Interest Research Group; Environmental Defense Fund; Alliance of Nurses for Healthy Environments; NRDC; Cape Fear River Watch

Q: ***In the final prioritization rule, EPA decided to remove the process known as 'pre-prioritization'. Do you agree with the reasoning behind this decision?***

Answer:
In reviewing the public comments on the proposed rule, it is clear that commenters shared diverse views on this provision that were often irreconcilable. I support EPA's decision to defer final action on this provision until there has been further discussion with the stakeholder community, including the additional public comment opportunity.

Q: ***What do you see as the goal for a 'pre-prioritization' phase?***

Answer:
I see this process as helping the Agency to identify potential candidates for prioritization. The prioritization process itself determines whether a particular chemical is designated as a Low-Priority and set aside, or as High-Priority and further evaluated. But as a matter of responsible implementation and given the tight statutory deadlines, the Agency needs to start binning chemicals earlier and identifying information needs. A pre-prioritization process should inform the information and data landscape for the tens of thousands of chemicals on the TSCA inventory, and give the public an additional opportunity to engage the Agency early in the process of reviewing existing chemicals.

Risk Evaluation Rule

Q: ***What is the status of lawsuits brought against this rule?***

Answer:
There have been three lawsuits brought against the Risk Evaluation Rule. To date (Sept 1, 2017) the Agency has not been made aware of the underlying basis of the litigation.

Background:
The Agency is currently working to consolidate the petitions in a single circuit, because they are currently in 3 different courts. The process will then go as follows: First he Agency will submit the petitions filed and served on the Agency to the Judicial Panel on Multidistrict Litigation. 28 U.S.C. § 2112(a)(1). The Panel then randomly selects a court from among those where petitions were filed in which all cases will be consolidated and the agency will file the record. Id. § 2112(a)(3).

Organizations suing: Safer chemicals healthy families; Alaska community action on toxics; Environmental health strategy center; Environmental working group; Learning Disabilities Association of America; Sierra club; Union of concerned scientists; United steel, paper and forestry, Rubber, manufacturing, energy, Allied industrial and service workers international union, AFLCIO/CLC; We Act for Environmental Justice; Asbestos Disease Awareness Organization; Vermont Public Interest Research Group; Environmental Defense Fund; Alliance of Nurses for Healthy Environments; NRDC; Cape Fear River Watch

Q: ***Please describe your understanding of the Agency's approach to identifying 'conditions of use' under TSCA.***

Answer:
"Conditions of use" must be interpreted in the context of the overall objective in TSCA: to ensure that within the statutory deadlines, the Agency is conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole, on the conditions of use that raise the greatest potential for risk. As stated in the Risk Evaluation framework rule, EPA interprets the statutory mandate to conduct risk evaluations and any

corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context.

Q: ***Do you believe the Agency's interpretation of 'conditions of use' is supported by Congressional intent?***

Answer:
Yes.

Background:
The statutory language provides the Agency with some discretion in identifying the uses that will be considered in a risk evaluation. These phrases include the statutory definition of 'conditions of use' - the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" and how conditions of use should be addressed in the scope document - "the conditions of use that the Agency expects to consider in a risk evaluation."

TSCA defines a chemical's "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). While EPA interprets this as largely a factual determination—*i.e.*, EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion as evidence by the phrase "as determined by the Administrator". As EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance – not just individual uses or activities – presents an unreasonable risk. In that regard, EPA will be guided by its best understanding, informed by legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal Congress intended EPA to consider in risk evaluations.

In developing the scope of the risk evaluation, TSCA section 6(b)(4)(D) requires EPA to identify "the conditions of use that the Agency expects to consider in a risk evaluation," suggesting that EPA is not required to consider all conditions of use. Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "*de minimis*" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

Q: ***Do you support the Agency's decision to define some of the key science terms/phrases in the final risk evaluation rule?***

Answer:
In response to comments received on the proposed risk evaluation rule, as well as to increase clarity, confidence, and transparency, it was imperative to include definitions for key science terms such as "best available science", "weight of the scientific evidence", and "reasonably available information". Given the overarching and inclusive principles in the final definitions, I don't believe that providing general definitions restricts flexibility or scientific advancement.

Background:
EPA has chosen to only define terms in this final rule that appear in the statute, including best available science, reasonably available information, and weight of the scientific evidence, among others.

Best available science. Section 26(h) of amended TSCA requires that "in carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science."

The definition codified in the rule originates from the Safe Drinking Water Act (SDWA) and is also included in the EPA's Information Quality Guidance and well as TSCA section 26(h), which identifies mandatory approaches to fulfilling the science standards under TSCA. By basing its definition of 'best available science' on these two sources, EPA believes that the Agency is remaining consistent with the current approach already used Agency-wide, while also acknowledging the specific standards under TSCA.

The final rule defines "best available science" as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

Additionally, EPA will consider as applicable: –

- The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;
- The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and;

- The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

Reasonably available information. TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is "reasonably available," but the statute does not further define this phrase. In the final rule, EPA defines "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation." Information that meets the terms of the preceding sentence is reasonably available information whether or not it is claimed as confidential business information.

Weight of the scientific evidence. The Agency is required by the statute to use a weight of scientific evidence approach in a risk evaluation and the Agency is codifying a definition of this term in this final rule. There are certain principles of weight of the scientific evidence that are universal, such as objectivity and transparency, and the general process, therefore EPA does not think that providing a general definition restricts flexibility or scientific advancement. For the purposes of this rule the definition EPA is adopting states: "Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." The bulk of the definition, aside from the phrase "applied manner suited to the nature of the evidence or decision" clarification, is taken directly from TSCA's legislative history. See Congressional Record at S3519, June 7, 2016. The additional phrase was added to be consistent with the concept that the components of its risk evaluations will be "fit-for-purpose," meaning that while EPA will always apply the principles contained in the definition, the depth or extent of the analysis will be commensurate with the nature and significance of the decision.

Q: ***What are your views on considering aggregate exposure in a risk evaluation?***

Answer:
Under TSCA, EPA is required to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered and the basis for that consideration. The decision to consider this type of exposure will necessarily be on a case-by-case basis, and must be supported by the best available science.

Background:
From the risk evaluation rule - Aggregate exposure means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways. This is consistent with the proposed rule and consistent with agency policy.

First 10 Chemical Risk Evaluations

Q: ***EPA has identified the first 10 risk chemicals for risk evaluations. Do you think these activities are on the right path?***

Answer:
EPA recently published the scope documents for these first 10 chemicals. As I understand it, the tight time considerations and lack of an opportunity for public comment, the Agency committed to publishing problem formulation documents for each of the first 10 chemicals at the end of this calendar year. I support this decision. These documents will further narrow the scope with respect to conditions of use and exposures to be considered, and further define the process of systematic review of the information that will inform the risk evaluation.

Q: ***Please describe your understanding of the Agency's approach to 'conditions of use' in these scope documents.***

Answer:
As I understand it, the final scope, which must specify the conditions of use that EPA expects to consider in the risk evaluation, will also identify whether particular conditions of use have been excluded as a result of this process, along with the Agency's rationale.

Q: ***Problem formulation documents for the first 10 risk evaluations are expected in December. What purpose do you believe these documents serve? How will these documents be different than the scopes?***

Answer:
My understanding is that the Agency's intent with the Problem Formulation step is to further refine and narrow the scope documents, particularly with respect to which conditions of use will be included in the risk evaluation and which will not. For example, the scope documents do not include an examination of existing regulations that are already in place to manage risks of a particular chemical, whereas the problem formulation documents will.

Q: ***The Agency has said it will not be examining legacy uses of Asbestos. Do you agree with this position?***

Answer:
Yes. The statutory mandate to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposure resulting from non-legacy uses.

Q: ***The Agency decided not to consider all routes of exposure to 1,4 dioxane in the scope document. Was this appropriate? (This was the topic of a May 23, 2017 letter from Senators Gillibrand and Schumer).***

Answer:
It is important to look into sources of contamination from 1,4-dioxane. I'm committed to protecting public health and will support the states to identify the appropriate steps to address the presence of 1,4-dioxane in water.

Background:
For 1,4-dioxane produced as a byproduct of reactions in the production of other chemicals, the EPA anticipates that 1,4-dioxane byproduct and contaminant issues will be considered in the scope of any risk evaluation of ethoxylated chemicals and is therefore not including it in the scope of the 1,4-dioxane risk evaluation. For example, Nonylphenol and Nonylphenol Ethoxylates (NP/NPE) are in the TSCA Work Plan and any 1,4-dioxane releases from NP/NPE manufacture, processing, use, or disposal will be evaluated then.

New Chemical Reviews

Q. ***What is the status of the backlog of new chemical premanufacture notification (PMN) reviews?***

Answer:
I understand that the Agency has eliminated the backlog, which as a result of the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, grew to almost 600 cases.

Background:

- TSCA requires anyone who plans to manufacture (including import) a new chemical substance for a non-exempt commercial purpose to provide EPA with notice before initiating the activity. This notice is known as a premanufacture notice (PMN).
- TSCA, as amended by the 2016 Lautenberg Chemical Safety Act, requires that EPA make an affirmative safety determination on a new chemical the subject of a PMN before a new chemical can come to market. EPA can require more information from chemical companies if it needs more information to make a safety determination.
- EPA must make a determination on the PMN within 90 days (extendable by another 90 days unilaterally by EPA and additionally through mutual consent of EPA and the PMN submitter).
- Determinations EPA may make on a PMN and resulting action EPA must take include:
    - In cases where EPA determines that a new chemical is not likely to present an unreasonable risk, EPA will notify the submitter of its decision (which allows them to commence manufacture) and publish its findings in the Federal Register.
    - If the Agency determines there is insufficient information to permit a reasoned evaluation of the human health and environmental effects of the chemical or if the chemical presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, EPA

must take action to restrict the chemical pending the development of needed information, i.e., via TSCA section 5(e) orders.
    - In cases were EPA determines that a new chemical or significant new use presents unreasonable risk of injury to health or the environment without consideration of cost or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation under the conditions of use, EPA may (1) limit the amount manufactured/processed/distributed in commerce or impose other restrictions on the substance via an immediately effective proposed rule under section 6 of TSCA, or (2) issue an order (under TSCA section 5(f)) to prohibit or limit the manufacture, processing or distribution in commerce to take effect on the expiration of the applicable review period.
- A backlog of new chemical review cases resulted from the new obligation to make affirmative safety determinations, including on chemicals undergoing various stages of review prior to the passage of the Lautenberg Act.

Q. ***How did EPA achieve this reduction in the backlog?***

Answer:
EPA deployed new staff and made other process changes to make the process faster and more efficient, while ensuring chemical safety.

Q. ***What process changes did EPA make in the new chemicals review process to help achieve this backlog reduction?***

A. I understand changes include:

- Where the intended uses in premanufacture notices (PMNs) raise risk concerns, EPA will work with submitters, and, if the submitters submit timely amended PMNs addressing those concerns, EPA will generally make determinations based on those amended submissions.
- Where EPA has concerns with reasonably foreseen uses, but not with the intended uses as described in a PMN, as a general matter, those concerns will be addressed through significant new use rules (SNURs), which require advance notification to EPA for the uses covered by the SNUR should they be intended and require an affirmative determination by EPA on the notified chemical similar to a determination needed for a PMN.

Q. ***How do you plan to balance facilitation of innovation with ensuring chemical safety in administering the new chemicals review program?***

Answer:
I will work to ensure the program implements Administrator Pruitt's commitment to being a partner in the regulatory process, and ensuring safety for health and the environment, while also

seeking ways to allow new chemicals to enter the market quickly, once EPA is assured that the chemical is not likely to present unreasonable risk for the intended and reasonably foreseen uses.

TSCA Confidential Business Information (CBI)

Q: ***EPA is required to review CBI substantiation at the time of submission and at other times. How will you ensure that the commitment to transparency that the new legislation calls for is being implemented?***

Answer:
I am committed to faithfully carrying out EPA's responsibilities under TSCA, as amended, including reviewing the substantiation of Confidential Business Claims and ensuring the proper balance between providing information to the public and protecting Confidential Business Information (CBI).

Background:
The Frank R. Lautenberg Chemical Safety for the 21st Century Act introduced new requirements relating to the submission of CBI, its management, and periodic reviews of CBI claims, including expiration of CBI claims. All CBI claims must be substantiated at the time the information claimed as CBI is submitted to EPA, except for those types of information exempt under TSCA section 14(c)(2). EPA must, with limited exceptions, review all CBI claims for chemical identity, as well as a representative sample of at least 25% of other claims within 90 days of receipt. Other CBI claims may also be reviewed by the Agency based on specific events, such as pursuant to a Freedom of Information Act (FOIA) request, when a substance is designated as a high priority or active substance, or when the Agency believes that disclosure would be important in implementation of TSCA section 6. Most CBI claims expire after 10 years unless the information submitter reasserts and re-substantiates the CBI claim. Some stakeholders have claimed that the previous statutory language allowed overly broad CBI claims that this limited public access to chemical information. Section 14 of TSCA, as amended, was entirely replaced and therefore many of the requirements are new and require significant changes to data systems, processes and procedures.

Safer Choice Program

Q: ***The Safer Choice program uses hazard criteria to evaluate chemicals. How can you determine that products are appropriately identified for participation in this program without considering exposure and using a risk based approach?***

Answer:
EPA engages in an open and transparent process to engage with all stakeholders and evaluates the physical and toxicological characteristics of chemicals to ensure that Safer Choice labeled products include the safest possible ingredients while still being effective.

Q: ***How does the Safer Choice program ensure that chemical manufacturers are appropriately engaged in developing the criteria?***

Answer:
My understanding is that EPA works with manufacturers and retailers to ensure appropriate engagement from both manufacturers and retailers.

Background:
Each chemical ingredient in a formulation has a function in making a product work - whether it is to aid in cleaning by reducing surface tension (surfactants), dissolve or suspend materials (solvents), or reduce water hardness (chelating agents). Safer Choice focuses its review of formulation ingredients on the key (environmental and human health) characteristics of concern within a functional class. This approach allows formulators to use those ingredients with the lowest hazard in their functional class, while still formulating high-performing products. The Safer Choice criteria are based on EPA expertise in evaluating the physical and toxicological properties of chemicals. Safer Choice applies the criteria using EPA research and analytical methods to ensure that Safer Choice products contain only the safest possible ingredients.

EPA has, at times, heard criticism that the Safer Choice labeling program can create de facto "retailer regulations" because retailers who participate may exert power over manufacturers to change formulations thus creating an imbalance in the business relationship. However, the Safer Choice program deliberately engages with and includes manufacturers as partners to ensure their constructive involvement in developing labeling requirements. If the program were to end, NGO's and/or retailers themselves would create their own labels resulting in a patchwork of requirements which would likely shift the control completely to NGOs and retailers.

Q: ***The fiscal year 2018 President's Budget eliminates all funding for the Pollution Prevention program which includes the Safer Choice program. Are you aware of the broad support for the Safer Choice program from both industry and NGOs?***

Answer:
Yes. I'm aware that industry has expressed significant support for the Safer Choice program and concern about its potential elimination in the FY 2018 budget. EPA received a letter from almost 200 partner companies and trade associations expressing concern with the potential elimination and support for the program.

Background:
Industry indicated that the program is an "invaluable resource to industry," that helps consumers, businesses, and procurement officers identify products with reduced environmental and health hazards while maintaining the same level of performance. Industry also spoke to the advantage of a robust national program over a patchwork of logo programs promoted by retailers and NGOs. Industry also noted the balance struck between protecting trade secrets and providing information. Finally, they noted that the costs of other programs are rising while Safer Choice remains affordable for the 500 small business industry partners.

Formaldehyde

Q. ***Industry stakeholders have expressed significant concerns about costs and impracticable aspects of the Formaldehyde Standards for Composite Wood Products regulation. How would you propose that EPA address these concerns?***

Answer:
My understanding is that EPA has recently published several actions amending this rule in response to stakeholder concerns. However, I'm committed to hearing additional stakeholder's concerns, reducing regulatory burden where appropriate, and clarifying requirements.

Background:
The Formaldehyde Standards for Composite Wood Products (TSCA Title VI)
On July 27, 2016, EPA finalized a rule to implement TSCA Title VI to reduce formaldehyde emissions from composite wood products. The statute established the same formaldehyde emission standards for composite wood products including hardwood plywood, medium-density fiberboard, and particleboard, as established by the CARB ATCM, directed EPA to address areas not included in CARB's standards and deferred to EPA to determine whether laminated products should be regulated.
Final Rule Implementing TSCA Title VI
On December 12, 2016 rule requiring composite wood products to be tested, certified, labeled and records kept, the rule also establishes a third-party certification program and includes procedures for the accreditation bodies (ABs) and third-party certifiers (TPCs).
Changes to final Rule
Compliance Dates
The final rule effective date was extended from February 10, 2017 to May 22, 2017 through a direct final rule and parallel proposal on May 24, 2017 to extend the compliance dates; however, negative comment was received so EPA has withdrawn the direct final rule and is now proceeding to issue a subsequent final rule.
Early Labeling
EPA has issued a direct final rule and parallel proposal to allow regulated composite wood products and finished goods that meet the formaldehyde emissions standards, and have been certified by an EPA-recognized TPC, to be voluntarily labeled as compliant as soon as compliance can be achieved before the emission standards, labeling, and recordkeeping compliance date.
Voluntary Consensus Standards
EPA will also soon issue a direct final rule and parallel proposal voluntary consensus standards incorporated by reference in the rule to newer versions of those same standards to allow regulated entities to use most current standards, consistent with CARB.

Lead
Q: ***There are significant concerns from constituents regarding the Renovation, Repair and Painting Rule requirements and implementation. What would you do to address these concerns?***

Answer:
I look forward to learning more about this rule and these concerns. I welcome a continuing dialogue on this issue with you and your office, as well as any interested stakeholders.

Q: ***EPA has been petitioned to update the lead hazard standards, but hasn't yet taken action. What is your position on this matter? Would you update the standards to reflect the best available science on lead?***

Answer:
I look forward to learning more about the issue and the underlying science. I understand that this matter is actively undergoing review by the Court. EPA and the petitioners filed briefs in January and oral arguments occurred in June. EPA is currently awaiting the court's decision.

Q: ***EPA never finalized a rule to address lead in public and commercial buildings, although doing so is statutorily mandated, and EPA committed to completing its work by March 31, 2017. The problem of lead contamination in this country is not going away, as evidenced by the crisis in Flint, MI. How do you intend to move forward on this important rulemaking?***

Answer:
I'm not familiar with the specifics of this rulemaking. However, I am cognizant of the dangers posed by lead and am fully committed to reducing instances of lead poisoning, where possible.

Background:
Stakeholders have been critical of the RRP rule due to costs of implementing the work practice and training requirements and for the amendment that removed the ability of homeowners to opt out of having contractors follow the requirements if no children or pregnant women live in the home. Stakeholders have also been critical of the economic analysis that estimated costs under the assumption that a test kit would be available to meet the positive and negative criteria set forth in the regulation. They argue that renovators are being made to follow the work practices when lead at the regulated level may not be present due to a "false positive" test result.
403 Hazard Standards litigation: On August 24, 2016, several plaintiffs filed a petition seeking a court order compelling EPA to issue a proposed rule within 90 days of that order, and a final rule within six months. Petitioners contend that EPA has unreasonably delayed its commitment to initiate a rulemaking to lower the hazard standard for lead in dust. On August 24, 2016, several plaintiffs filed a petition seeking a court order compelling EPA to issue a proposed rule within 90 days of that order, and a final rule within six months. Petitioners contend that EPA has unreasonably delayed its commitment to initiate a rulemaking to lower the hazard standard for lead in dust. On January 17, 2017, EPA filed its brief and declaration; petitioner's response brief was filed on January 27, 2017; oral argument occurred June 12, 2017. EPA is waiting on a decision from the court.

Public and Commercial Buildings Litigation: Litigants informed DOJ/OGC in December 2016 that they intend to reactivate the litigation instead of negotiating a new settlement deadline when EPA missed the previous settlement deadlines. Litigants informed DOJ/OGC in December 2016 that they intend to reactivate the litigation instead of negotiating a new settlement deadline. No further discussions with litigants have occurred and EPA missed the March 31, 2017 deadline.

Polychlorinated Biphenyls (PCBs)

Q: ***PCBs have been identified in school buildings across the country, threatening the health and safety of our children. What would you do to address the dangers of PCBs in schools?***

Answer:
Providing accurate and consistent technical information to the relevant states and localities is a key first step. EPA has Q&A guidance on addressing PCBs in school buildings that should be helpful those cities dealing with legacy PCB contamination. Where appropriate, OCSPP can and should review its continued-use authorizations for certain uses of PCBs.

Background:
PCBs were used in hundreds of industrial and commercial applications from 1929 until the manufacture, processing, distribution in commerce and use of PCBs was banned under Section 6(e) of TSCA in 1979. TSCA Section 6(e) provides that, if it can be demonstrated that there is no unreasonable risk of injury to health or the environment, then EPA may authorize continued uses of PCBs by regulation and PCBs are still authorized for use in certain applications including electrical equipment. OCSPP oversees the continued use of PCBs in buildings and equipment, while the Office of Land and Emergency Management (OLEM) oversees the disposal of PCBs. Schools built or renovated between 1950-1979 have widespread use of polychlorinated biphenyls (PCBs) containing building materials (e.g., non-liquid PCBs in caulk and paint, and liquid PCBs in fluorescent light ballasts (FLB)). EPA is aware of a number of incidents involving releases of PCBs from FLBs in schools that have occurred across the country including hundreds of incidents in New York City, Los Angeles and elsewhere. EPA sent a proposed rule to the Office of Management and Budget (OMB) in late 2016 to end the use authorization for PCB-containing fluorescent lights ballasts (FLB) in schools and daycare centers after December 31, 2020. Per OMB request, this proposal was withdrawn in January 2017.

Per- and Polyfluoroalkyl Substances (PFOA/PFAS)

Q: ***Certain geographical hotspots have PFOA/PFAS exposures that are higher than the general population (e.g. Parkersburg, WV; Decatur, AL; Hoosick Falls, NY)? How would you ensure that these hotspots are adequately protected from PFOA/PFAS exposures?***

Answer:
I understand that in 2006, EPA, in cooperation with eight major leading companies in PFAS industry, launched a PFOA Stewardship Program with the goal of eliminating these chemicals from emissions and products by 2015, and that all participating companies have met the PFOA Stewardship Program goals. The amendments to TSCA provided OCSPP with improved

authority to regulate existing chemicals. However, I would need to learn more about what other actions are potentially underway, and other options we may have under our new statutory authority to reduce exposures, after I have joined EPA and been briefed on this issue.

Q: ***The chemical GenX has been detected in the Lower Cape Fear River in NC, a drinking water source for thousands of North Carolinians. The finding appears in direct conflict with an EPA consent order that mandates minimal releases to water. The company is claiming their releases fell under a "byproduct" loophole. EPA has yet to take action. What would you do to ensure this situation is remedied and does not occur again?***

Answer:
I understand that EPA is already investigating the company's compliance with the requirements of a 2009 Consent Order issued under TSCA section 5 requiring control of releases to the environment associated with production of GenX at the company's Fayetteville, N.C. EPA is also reviewing additional toxicity data submitted by the company, as required under the Consent Order, and is updating the risk assessment using more recent production data and the additional GenX toxicity data.

Q: ***Do you agree with the commitment made by EPA Administrator Pruitt during his confirmation hearing regarding the importance of working quickly to undertake further testing for PFOA and potentially regulating or banning these chemicals?***

Answer:
I support the commitment made by Administrator Pruitt to address this issue.

Background:
In 2006, EPA, in cooperation with eight major leading companies in PFAS industry, launched the 2010/2015 PFOA Stewardship Program with the goal of eliminating these chemicals from emissions and products by 2015. All participating companies have met the PFOA Stewardship Program goals EPA remains concerned about the ongoing uses of PFOA and related chemicals that are still available in existing stocks or are being newly introduced by companies not participating in the PFOA Stewardship Program.

On January 21, 2015, EPA proposed a Significant New Use Rule (SNUR) that requires manufacturers (including importers) and processors of PFAS chemicals, including as part of articles, to notify EPA at least 90 days before starting or resuming new uses of the chemicals in any products.

PFAS chemicals lack evaluated, quantitative toxicity information and validated analytical methods. The lack of information and methods makes it difficult for EPA Offices and Regions to make evidence-based decisions regarding potential human health risks from ongoing or future exposures

The N.C. Department of Environmental Quality (DEQ), in consultation with the N.C. Department of Health and Human Services (DHHS), is leading a state investigation into reports of an unregulated chemical known as GenX (replacing PFOA) in the lower Cape Fear River in

N.C. Chemours, the company that produces the chemical at its facility in Fayetteville, N.C., maintains that it is currently capturing, removing and disposing of wastewater that contains the byproduct GenX. EPA's health advisory for PFOA and PFOS combined is 70 ppt. There is no EPA health advisory level for GenX. NC DEQ and DHHS are continuing to investigate the levels of GenX in the lower Cape Fear region. On July 17, NC Governor Cooper sent a letter to EPA urging EPA to set limits, revisit the consent order, and require Chemours to submit additional studies on GenX.

January 18, 2017 Testimony excerpt:
Mr. Pruitt. The TSCA authority that has been granted by this body, you and I talked about that in your office, PFOA needs to be addressed quickly, even under the Safe Drinking Water Act as well.
Senator Gillibrand. Will you commit to doing that work?
Mr. Pruitt. Yes, Senator.

TSCA Section 6 Rules

Q: ***EPA has proposed regulations to address unreasonable risks from Trichloroethylene and paint removers. Will you expeditiously finalize those proposed rules?***

Answer:
I'll need to be briefed further on this issue. I understand that EPA is in the process of reviewing comments received on these two proposals to determine potential paths forward.

Q: ***If EPA's proposal on Methylene Chloride was finalized would it have prevented the recent death in Ashland City TN?***

Answer:
I am not aware of the details regarding the investigation into this death and therefore am unable to comment.

Background:
TCE is a volatile organic compound (VOC) and hazardous air pollutant (HAP) classified as a human carcinogen. In the June 2014 TSCA Work Plan Risk Assessment for TCE, EPA identified acute and chronic non-cancer and cancer risks associated with TCE use in commercial degreasing and some consumer uses.

Methylene chloride is a volatile solvent that is a probable human carcinogen used in consumer and commercial paint and coating removal; at least one worker death annually is attributed to methylene chloride in bathtub refinishing. NMP is a developmental toxicant presenting risks of fetal death and decreased birthweight; it is used in consumer and commercial paint and coating removal and is often a substitute for methylene chloride in consumer uses.

On December 7, 2016, under section 6(a) of TSCA, EPA proposed to ban uses of TCE as an aerosol degreaser and for spot cleaning in dry cleaning facilities as a result of health risks

identified in a 2014 TSCA Chemical Work Plan Chemical Risk Assessment for TCE. The comment period closed on March 16, 2017, and EPA received 28 comments on the proposed rule.

On January 19, 2017, under section 6(a) of TSCA, EPA proposed to ban the use of TCE in commercial vapor degreasing as a result of health risks identified in a 2014 TSCA Chemical Work Plan Chemical Risk Assessment for TCE. The comment period closed on May 19, 2017, and EPA received 544 comments on the proposed rule. This proposed rule and a proposed rule on TCE in spot cleaners in dry cleaning and consumer and commercial aerosol spray degreasing are planned to be finalized together in one action.

On January 19, 2017, under section 6(a) of TSCA, EPA proposed to regulate NMP and methylene chloride in paint and coating removal. The comment period closed on May 19, 2017, and EPA received 1,401 comment on the proposed rule.
TSCA, as amended, allowed for these proposals to move forward under the risk assessments that had already been completed prior to the new prioritization and risk evaluation processes in the amended statute.

On August 30, 2017, EPA published a Federal Register Notice announcing that we will a workshop on the use of methylene chloride in furniture refinishing on September 12, 2017. EPA has heard about the death of a worker employed as a bathtub refinisher, which appears to be associated with exposure to methylene chloride. Kevin Anthony Hartley, age 21, of Ashland City, Tennessee died on April 28, 2017. OSHA is investigating this death.

Enforcement of Regulatory Requirements

Q. ***What are your views on the role of enforcement in effective implementation of regulatory requirements?***

Answer:
I believe a robust enforcement program is essential to support the effective implementation of regulatory requirements and to help unsure a level playing field. I also believe compliance assistance is important in facilitating regulatory compliance and thus reducing the need for enforcement responses.

Regulatory Burden Reduction Executive Order and TSCA Implementation

Q: ***How do you believe the Executive Orders issued by this Administration on burden/regulation reduction will impact TSCA implementation?***

Answer:
I believe the Executive Orders will have no impact on the effective implementation of TSCA. I expect that the Executive Orders will help ensure that necessary regulations are designed to be

effective and efficient in reaching regulatory goals, and those not necessary, effective, or efficient will be repealed, replaced, or modified.

Background:
On January 30, 2017, President Trump issued EO 13771 on Reducing Regulation and Controlling Regulatory Costs. In sum, it includes requirements including that:

- agencies identify two existing regulations to be repealed whenever an agency proposed or otherwise promulgates a new regulation
- for fiscal 2017, agencies must ensure that the total incremental costs of all new regulations, including repealed regulations, to be finalized this year must be no greater than zero, unless otherwise required by law or consistent with advice provided in writing by the Director of OMB.
- Any new incremental costs associated with new regulations must, to the extent permitted by law, be offset by the existing costs associated with at least two prior regulations.

On February 24, 2017, President Trump issued EO 13777 on Enforcing the Regulatory Agenda; it is designed to reduce the regulatory burdens agencies place on the American people, and it directs agencies to take several activities to further this goal, including:

- the designation of a Regulatory Reform Officer and the establishment of a regulatory reform task force which is charged with evaluating existing regulations and making recommendations (informed by stakeholder input) to the Administrator regarding those that can be repealed, replaced, or modified to make them less burdensome.

Does EPA have enough information to evaluate the risk of most chemicals?

Q: ***Do you think EPA has enough information to evaluate the risks of most chemicals?***

Answer:
This is a chemical-by-chemical issue due to the heterogeneity of chemicals and their specific uses covered under TSCA. However, if for a particular chemical, the Agency determines there is not enough information, the amended law provides authorities to obtain additional information in order to conduct a comprehensive risk evaluation.

Background:
This lack of information was known by the drafters of the amended TSCA, and the amended law gives the Agency more flexibility and authority to obtain the information needed to fully evaluate chemicals for their risks to human health and the environment. For new chemical pre-manufacturer notices, the law provides the provision for the Agency to determine that there is not enough information, and the law also provides additional authorities to obtain additional information when necessary for existing chemical evaluations.

OFFICE OF SCIENCE COORDINATION AND POLICY (OSCP)

Science Coordination

Q: ***The Office of Chemical Safety & Pollution Prevention (OCSPP) is a government leader in the development and regulatory use of computational toxicology (CompTox) and high throughput screening (HTS) and testing of chemicals. What are your thoughts on this emerging science and what is your commitment to the further integration of alternative approaches into OCSPP endeavors?***

Answer:
Use of these technologies allows more chemicals to be assessed in fraction of the time as traditional methods, for a fraction of the cost. The use of HTS and CompTox in EPA chemical assessments is especially exciting because it can significantly reduce the costs and burdens on the regulated community. This will also add to the body of knowledge about mechanisms, mode of adverse outcomes supporting the relevancy of decisions. This will be especially important for EPA programs that have been traditionally "data poor" (*e.g.*, OCSPP's Office of Pollution Prevention & Toxics (TSCA) and EPA's Office of Water). The Endocrine Disruptor Screening Program (EDSP) has already announced that it will accept computational toxicological data as an alternative for three of its eleven traditional EDSP Tier 1 guideline studies. Development of the High Throughput (HTS) alternatives for the remaining eight EDSP Tier 1 guidelines are underway. The use of Computational toxicology will allow the OCSPP to implement TSCA more quickly and efficiently.

Background:

- High throughput assays are automated methods that allow for a large number of chemicals to be rapidly evaluated for a specific type of bioactivity at the molecular or cellular level. This approach, which can help identify compounds that may modulate specific biological pathways, was initially developed by pharmaceutical companies for drug discovery. The results of these methods provide an initial understanding of a biochemical interaction and possible role of a chemical in a given biological process(es).
- Computational Toxicology, or "CompTox", uses computer models and high throughput cell-based methods in place of traditional animal-based chemical testing of apical endpoints.
- High throughput assays can be run for a range of test chemical concentrations and produce concentration-response information representing the relationship between chemical concentration and bioactivity. The concentration-response data from multiple assays can be mathematically integrated in a computational model of a biological pathway, providing values representative of a chemical's bioactivity in that pathway (*e.g.*, estrogen receptor pathway). To reduce non-specific results, the computational model can use results from multiple assays and technologies to predict whether a chemical is truly bioactive in the pathway being evaluated and does not get confounded by nonspecific interference with a single assay.

Q: ***Another OCSPP area of emerging science is the use of a Systematic Review Framework and methods to extract, review and integrate existing data and literature. Please describe its***

advantages and how you would leverage this approach to improve efficiency and transparency in the program and throughout EPA.

Answer:
Systematic Review is an important tool that increases the transparency and the reproducibility of the scientific/regulatory decisions the Agency makes. The Systematic Review approaches will inform the registration and review of pesticides and is critical to the continued evaluation of industrial chemicals under TSCA.

Background:

- Systematic Review, as described in the National Research Council Review of EPA's Integrated Risk Information System (IRIS) Process (2014), is "a scientific investigation that focuses on a specific question and uses explicit, pre-defined scientific methods to identify, select, assess, and summarize the findings of similar but separate studies." Simply put, systematic review is a method of determining which scientific studies can and should be reviewed to make decisions about a specific scientific question.
- To answer important environmental health science questions, federal agencies and other entities have developed several approaches to implement systematic review. These approaches share a common pre-defined framework that include:
  - Defining a specific research question
  - Developing clear search strategy to identify relevant studies
  - General agreement on inclusion and exclusion criteria for relevant studies, and individual study evaluation criteria
  - Integrating data to answer the research question
  - Identification of biases and confounding results
- OCSPP's OSCP leads development of the OCSPP systematic review framework to harmonize approaches for the collection, evaluation, and integration of data for human health and ecological risk assessments in OCSPP.
- OCSPP's OSCP co-leads EPA's Systematic Review Community of Practice (CoP).
- The TSCA Framework rules emphasize the importance of systematic review and transparency.

Q: ***Describe your vision of how OCSPP will foster an improved Quality Assurance (QA) program including auditing Good Laboratory Practices (GLPs) of Industry test data.***

Answer:
The Agency has proposed changes to the Pesticide Registration Improvement Act (PRIA) (a.k.a. PRIA 4) for augmentation (via fees) for both GLP & PRIA programs. This GLP Audit Program will cover both national as well as test data submissions conducted outside the United States.

Background:

- EPA's Good Laboratory Practice Standards (GLPS) compliance monitoring program ensures the quality and integrity of test data submitted to the Agency in support of a pesticide product registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), section 5 of the Toxic Substances Control Act (TSCA),

and pursuant to testing consent agreements and test rules issued under section 4 and 5 of TSCA.

- Data obtained through laboratory inspections and data audits is used by the Agency to regulate the use of pesticides and industrial chemicals.
- FIFRA amendments passed by Congress in 2004 created a registration service fee system for applications for specific pesticide registration, amended registration, and associated tolerance actions. The goals of this fee system are to:
  - Create a more predictable evaluation process for affected pesticide decisions, and
  - Couple the collection of individual fees with specific decision review periods.
- The 2004 amendments are also known as the Pesticide Registration Improvement Act of 2003 (PRIA).
- PRIA fees have been reauthorized twice, most recently by the Pesticide Registration Improvement Extension Act (PRIA 3). This reauthorization expires September 30, 2017.
- PRIA 4 is pending before the current Congress.

Q: ***Scientific Integrity is an important part of the foundation for the use of science in decision-making for the Federal Government (especially in a regulatory setting). The independence of scientific investigation & evaluation from political manipulation and the correct attribution of intellectual contribution & providing a "safe haven" for dissenting scientific opinion has become increasingly important to EPA. Discuss how you plan to ensure Scientific Integrity in OCSPP.***

Answer:
EPA bases all decisions on sound science. Science cannot be considered "sound" unless it is 100% founded on Scientific Integrity principles (objectivity, clarity, reproducibility and utility). Scientific Integrity remains integral to all science and regulatory decisions within OCSPP and it will continue to be so under my watch.

Background:

- Scientific Integrity results from adherence to professional values and practices, when conducting and applying the results of science and scholarship. It ensures:
  - Objectivity
  - Clarity
  - Reproducibility
  - Utility
- Scientific Integrity is important because it provides insulation from:
  - Bias
  - Fabrication
  - Falsification
  - Plagiarism
  - Outside interference
  - Censorship
  - Inadequate procedural and information security

Q: ***How do you intend to improve Science Coordination within OCSPP, within EPA, and within the Federal Government? How do you intend to improve Science Coordination internationally and with the regulated community?***

Answer:
The emerging science within OCSPP (HTS, CompTox, Systematic Review, Cheminfomatics, etc.) will be coordinated with other parts of the Agency to leverage/maximize its use. I will conduct outreach to the regulated community to hear underrepresented opinions and concerns. I will promote the United States' tremendous scientific expertise to our international partners and encourage harmonization of regulatory frameworks to provide a greater certainty for the regulated community.

Q: ***How do you intend to continue and improve the Endocrine Disruptor Screening Program (EDSP)?***
Answer:
I will follow on with the success of the implementation of High Throughput Screening (HTS) and CompTox approaches into the EDSP based on appropriation support from Congress. Current activities within the EDSP include the continued transition to the use of HTS and CompTox tools to screen thousands of chemicals for endocrine activity, establishing policies and procedures for screening and testing, exploring approaches to predict other toxicological endpoints/outcomes, and evaluating data to ensure chemical safety by protecting public health and the environment from endocrine disrupting chemicals.

Background:

- The Endocrine Disruptor Screening Program (EDSP) prioritizes, screens and tests pesticides and other environmental contaminants for potential effects on estrogen, androgen, and thyroid hormone systems in humans and wildlife.
- The EDSP was mandated by the Food Quality Protection Act (FQPA) of 1996.
- The FY 2018 President's budget eliminates programs that are mature, duplicative, or can be absorbed into other programs, are equally conducted or eligible under other programs, or are or could be state and local responsibilities.
- The Endocrine Disruptor Screening Program (EDSP) is a mature program that was established in 1996 under authorities contained in the Federal Food, Drug and Cosmetic Act (FFDCA) and the Safe Drinking Water Act (SDWA) amendments.
- The *in vitro* high throughput and computational model alternatives provide an accurate quantitative measure of specific endocrine receptor binding bioactivity and mechanisms that can serve as alternatives to the current Tier 1 estrogen receptor (ER) binding, ER transactivation (ERTA) and uterotrophic assays.

Science Peer Review (FIFRA SAP and TSCA SACC)

Q: ***How can the EPA assure stakeholders and the public that it is relying upon the best available peer reviewed scientific and technical data when data/models/tools may not be easily identified or made available to the public either because of Confidential Business Information***

(CBI)/Intellectual Property (IP) claims or because limited information is available in peer-reviewed journals?

Answer:
Science is the backbone of EPA's decision-making. EPA relies upon the integrity of the science to accomplish its mission to protect human health and the environment. EPA's scientific integrity efforts include focusing on the promotion of a culture of transparency throughout the Agency; the release of scientific information to the public; and the consistent use of peer review and federal advisory committees (FACs). The Agency will continue its efforts to improve public participation activities by expanding its utility in the use of the federal register docket, the FIFRA SAP and SACC websites, systematic review process and adherence to Agency guidelines and procedures. In addition, the Agency continues to promote open access and public accessibility to both the government-funded intramural and extramural data.

Background:

- EPA's Scientific Integrity Policy provides a framework to promote scientific and ethical standards and to create a proactive culture to support them.
- Scientific integrity helps to build public support. People are more likely to support the Agency if they can trust the quality and integrity of its work.

Q: ***In previous years, stakeholders have expressed concerns that EPA's Federal Advisory Committee meeting processes and approaches are inconsistent throughout the Agency. These concerns include the selection of peer review members of various panels (i.e., FIFRA SAP, SAB) and the consideration of responses to public and peer review comments. Can you assure the Agency will operate consistently within its FACA meeting processes/procedures?***

Answer:
Yes, certainly. While many FACA committees may have unique statutory authorities related to their mission, objectives, scope of activity and general operational characteristics such as membership and designation have to be consistent with FACA rules. Each committee must file an active charter which consists of the estimated number of members, a description of the expertise required, and/or groups to be represented in order to achieve a balanced diverse membership. Due to the increase in public interest and participation in our FACs, the Agency has expanded its use of logistical and administrative meeting support services to compile and process voluminous comments in support of its meetings. The Agency will continue to adhere to the FACA guidelines and procedures in promoting accountability to the committee's charge and to the public.

Background:

- FACA is the Federal Advisory Committee Act (FACA) of 1972.
- The selection of committee members is made based on FACA's requirements and specific statutory authority of a given committee along with the potential committee member's background, experience and qualifications.
- FACA requires that committee memberships be "fairly balanced in terms of the points of view represented and the functions to be performed."

- In balancing committee memberships, agencies are expected to consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee.

Q: ***Peer review is important to the quality assurance process. How will you ensure the EPA's OCSPP will have a robust quality assurance program that evaluates whether its peer review recommendations and public comments are completely and adequately addressed?***

Answer:
Based on the 2017 Office of Inspector General's (OIG) report, the OIG determined EPA's system of controls to manage the recommendations and advice from FACs to be effective. The OIG also determined the Agency could improve its transparency to the public. To strengthen the agency's system of controls and improve public transparency, I would ensure posting all responses to an online platform in the format of a response to comments/reconciliation memorandum document, as per the EPA Peer Review Handbook (2015, 4th Edition).

Background:

- Refers to the March 13, 2017 Office of Inspector General Report entitled "EPA Has Adequate Controls to Manage Advice From Science and Research Federal Advisory Committees, but Transparency Could Be Improved Report No. 17-P-0124".

Q: ***How will you ensure that the Agency's peer review process is void of conflicts of interests in the evaluation of complicated scientific issues?***

Answer:
The Agency will continue to adhere to applicable federal ethics statues and regulations when selecting scientists as Special Government Employees (SGEs) [non-government employees] or Regular Government Employees (RGEs). SGEs/RGEs must complete/submit financial disclosure provisions of the Ethics laws. Each candidate's financial disclosure forms will be evaluated by the Designated Federal Official (DFO), Executive Secretary of the committee, and Deputy Ethics Official for OSCP to determine whether there are conflicts of interest (COI) and/or appearance of lack of impartiality. Review of additional information will also be evaluated to determine any appearance of a lack of impartiality. Furthermore, candidates are evaluated in accordance with the following guidance and databases: EPA Federal Advisory Committee Act Review Handbook; House and Senate Registry Databases (listing of all federally registered lobbyists); Google and PubMed Searches, individual social media searches (*e.g.*, LinkedIn).

Background:

- FACA candidates are subject to applicable federal ethics statues and regulations including the financial disclosure provisions of the Ethics in Government Act (5 U.S.C. §§ 101-111) and 5 C.F.R. Part 2634.